

ORIGINAL

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

[UNDER SEAL],

Civil Action, File No. _____

Plaintiffs,

CV 17 - 02141 VAP (Ex)

v.

[UNDER SEAL],

Filed in Camera pursuant to
31 U.S.C. § 3730(b)(2)

Defendants.

COMPLAINT FOR DAMAGES and
INJUNCTIVE RELIEF
under 31 U.S.C. § 3730
FALSE CLAIMS ACT

JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF UNDER 31 U.S.C. § 3730
FALSE CLAIMS ACT

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

United States of America *ex. rel.* Edwin Gvalevech,
State of California *ex rel.* Edwin Gvalevech, and

Civil Action, File No.

CV 17-02141 VAP (E)

Edwin Gvalevech,
Plaintiffs/Relator,

**Filed In Camera pursuant to
31 U.S.C. § 3730(b)(2)**

v.

Kroger Specialty Pharmacy, Inc.
Kroger Specialty Pharmacy CA 2, LLC,
ERL Medical Corporation,
Emmanuel R. Lim, MD,
Douglas Davies, M.D.,
Louis Flores, MD, and
The Doctor Health Center, Inc.,

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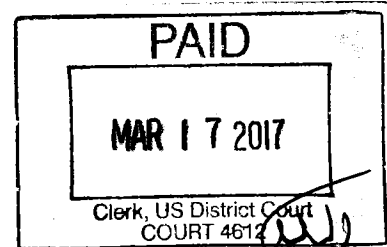


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Plaintiffs United States of America *ex rel.* Edwin Gvalevech, State of California *ex rel.* Edwin Gvalevech, and Plaintiff Relator Edwin Gvalevech, through their attorneys, Cross Law Firm, SC by Nola J. Hitchcock Cross and Louis J. Cohen, a Prof. Corp., by Louis Cohen, complain and allege as follows:

I. INTRODUCTION TO THE FRAUD

1. **Kroger Specialty Pharmacy, Inc.** f/k/a Modern HC Holdings Inc. operates a specialty retail pharmacy in California, **Kroger Specialty Pharmacy CA 2, LLC** f/k/a ModernHEALTH Specialty Ad-Rx, LLC (jointly referred to herein as “**ModernHEALTH**” except as otherwise noted) that focuses on dispensing drugs to some of the country’s most vulnerable populations, including those with HIV AIDS and others for whom the most potentially dangerous legal drugs may be medically necessary.
2. Such drugs are classified within Schedule II of the Controlled Substances Act (“CSA”), 21 U.S.C. §§801, *et seq.*, the provisions of which are enforced by the United States Drug Enforcement Agency (“DEA”).
3. As a specialty pharmacy, **ModernHEALTH** partners with provider clinics and physicians who focus on treating vulnerable populations. This symbiotic relationship between **ModernHEALTH** and providers is based on their mutual interest to increase their receipts from the public fisc resulting from prescribing, dispensing, and billing for CSA controlled substances, often in amounts and frequency that are not reasonable or medically necessary.
4. **ModernHEALTH** partners with Defendants **ERL Medical Corporation, Inc.**, **Emmanuel Lim, M.D.**, **Douglass Davies, MD**, **The Doctor Health Center, Inc.** d/b/a “the

doctor,” and **Louis Flores, MD** (collectively, “**Defendant Prescribers**”), as well as with many other providers set forth in detail below.

5. By reliably filling the prescriptions written by **Defendant Prescribers** and others on a no-questions-asked basis, regardless of red flags indicating a lack of medical necessity and regardless of DEA regulations requiring pharmacists to report to the DEA providers who write prescriptions for medically unnecessary controlled substances, Defendant **ModernHEALTH** sought to and successfully did induce **Defendant Prescribers** and others to refer their patients exclusively to **ModernHEALTH** for their expensive HIV medication and other drugs, including medically unnecessary CSA Schedule II through V controlled substances.

6. Through this kickback scheme, **ModernHEALTH**, agrees to fill all prescriptions written by its partner providers in return for the providers directing their patients to utilize **ModernHEALTH** exclusively for all of their prescriptions.

7. In addition, knowing that their prescriptions, including those that are all or partially medically unnecessary, will be filled, patients use the **Defendant Prescribers** as their physicians, despite in some cases having to travel long distances from their residence out of town to the **Defendant Prescribers’** clinics, because the patients expect and receive prescriptions for medically unnecessary re-saleable controlled drugs from these providers and they have come to rely on **ModernHEALTH** to fill the prescriptions without questioning their reasonableness or medical necessity with regard to the size, duration, and combination of prescriptions.

8. This kickback scheme between the **Defendant ModernHEALTH** specialty pharmacy and the **Defendant Prescribers** and others results in a huge loss to California and the federal government because the government healthcare plans cover the cost of the expensive

controlled drugs through their various healthcare programs, including Medicare, MediCal, and California's AIDS Drug Assistance Program ("ADAP").

9. For example, **Defendant LimKeith** refers patients with prescriptions for some of the most expensive drugs in the world, such as Harvoni ®, a Hepatitis C drug sold by manufacturer Gilead Sciences, Inc., at approximately \$94,000 for a 12-week prescription.

10. Specialty pharmacies like **ModernHEALTH** receive approximately \$2,600 to \$3,100 per patient per prescription to dispense the Hepatitis C drug, Harvoni ®.

11. The **Defendant Prescribers** often prescribe medically unnecessary but dangerous, addictive, saleable street drugs, such as oxycodone, along with such medically necessary HIV prescriptions. In turn, **Defendant ModernHEALTH** specialty pharmacy dispenses all such controlled substance prescriptions without question or hesitation.

12. Both the providers and the pharmacy increase their patient populations and their billings to government healthcare programs as patients come from far and wide to frequent the Defendant prescribers and Defendant specialty pharmacy.

13. As part of the kickback scheme to bill the government for unreasonable, medically unnecessary, and potentially dangerous drugs, **ModernHEALTH** requires its pharmacists to dispense prescriptions written by the **Defendant Prescribers** and other similarly egregious prescribers without even attempting to meet their "**corresponding responsibility**" to ensure, prior to dispensing and billing for the drugs, that prescriptions for regulated drugs have been written pursuant to the prescribers' actual, substantiated, legitimate medical judgement and that the prescription is both reasonable and medically necessary.

14. In addition, **ModernHEALTH** splits and extends prescriptions without medical authority solely for the purpose of circumventing the ADAP requirements for payment and fraudulently avoids prior authorization requirements.

15. This case involves significant threats of patient harm up to and including death and the corresponding likelihood of enhanced costs to the government for related additional treatment, as Defendants in this case epitomize the dangerous confluence of corporate greed and the overprescribing of controlled substances in perpetuating the growing opioid epidemic.

II. STATEMENT OF THE CASE

16. This action is brought on behalf of the **United States of America** and the **State of California** by **Relator Edwin Gvavech** to recover all damages, penalties and other remedies established by and pursuant to 31 U.S.C. §§3729-3733 and Cal. Gov't Code § 12650-56, and on behalf of Relator himself to claim entitlement to a portion of any recovery obtained by the United States of America and/or California *qui tam* plaintiffs as authorized by 31 U.S.C. §3730 and Cal. Gov't Code § 12651 and for damages pursuant to 31 U.S.C. §3730(h) for retaliatory harassment, threats and discrimination.

17. Relator brings this action to impose liability upon Defendants for violations of 31 U.S.C. §3729 of the federal False Claims Act ("FCA") and Cal. Gov't Code § 12651, the California False Claims Act ("CFCA"). Defendants' liability arises from their submission or caused submission to the **United States of America** and/or **State of California** of false and fraudulent claims for monetary payment for the sale of drugs regulated as Schedule II under the Controlled Substances Act, 21 U.S.C. §§801, *et seq* ("CSA").

18. Defendant pharmacy **ModernHEALTH** sells drugs to individuals entitled to healthcare coverage through Medicare, Medicaid, and California's AIDS Drug Assistance

Program (“ADAP”) benefits. Defendant **ModernHEALTH** submits or causes the submission of claims for payment for such drug sales to the government healthcare plans. Such claims were and are fraudulent due to Defendants’ schemes to violate and its violations of conditions of payment with Medicare, Medicaid, and ADAP, including compliance with laws and regulations governing the dispensing, control, sale, billing, and disbursement of Schedule II controlled substances and other drugs. 21 U.S.C. §§ 812, 829.

19. Defendants **ERL Medical Corporation, Inc., Emmanuel Lim, M.D., Douglass Davies, MD, The Doctor Health Center, Inc. d/b/a “the doctor,” and Louis Flores, MD** (collectively, “**Defendant Prescribers**”) likewise falsely represented and continue to represent that prescriptions for CSA Schedule II drugs they wrote for beneficiaries of Medicare, Medicaid, and ADAP were reasonable and medically necessary and written in compliance with Medicare, Medicaid, ADAP, and other laws and regulations governing such drugs. In turn, the **Defendant Prescribers** submitted or caused to be submitted to the government claims for payment of such drugs.

20. Defendants’ liability also arises from their false express and implied certification of compliance with the said laws and regulations governing their prescribing and dispensing of CSA Schedule II drugs.

III. PARTIES

A. Plaintiff/Relator and Government Plaintiffs

21. **Plaintiff Relator Edwin Gvalevech** is a resident of the State of California, County of Los Angeles, City of Montebello. At all material times, Gvalevech was and is a pharmacist licensed in the State of California and employed by Defendant **ModernHEALTH** as a Pharmacist

in **ModernHEALTH**'s Los Angeles, California facility, "Ad-Rx" located at 6240 Wilshire Boulevard, Los Angeles, California 90048.

22. **Relator** brings this action on behalf of the **United States of America** pursuant to 31 U.S.C. § 3730(b)(1). The **United States of America** is a sovereign country whose Department of Health and Human Services ("DHHS") and Centers for Medicare & Medicaid Services ("CMS") administer the AIDS Drug Assistance federal grant program.

23. **Relator** also brings this action on behalf of the **State of California** pursuant to Cal. Gov't Code section 12651 *et seq.* California's Department of Health Care Services administers the state's Medicaid and ADAP programs, both of which are partially state-funded and partially federally funded.

B. Defendant Specialty Pharmacies

24. Axiom Pharmacy Holdings, Inc., a wholly owned subsidiary of Kroger Co., purchased 100% of the outstanding shares of ModernHEALTH Specialty Ad-Rx LLC's parent company Modern HC Holdings, Inc. for \$407 million in a merger. The transaction closed on September 2, 2016, and the merged companies do business as **Kroger Specialty Pharmacy Inc.** f/k/a Modern HC Holdings, Inc. d/b/a **ModernHEALTH**, a closely held foreign stock corporation, with its principal place of business located at 550 Technology Park, Lake Mary, Florida 32746. Its registered agent, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service, is located at 2710 Gateway Oaks Drive, Suite 150N, Sacramento, California 95833.

25. **Defendant Kroger Specialty Pharmacy CA 2, LLC** f/k/a ModernHEALTH Specialty Ad-Rx, LLC is a limited liability corporation with a principal place of business located at 6435 Hazeltine National Drive, Suite 140, Orlando, Florida 32822. Its registered agent is

unknown. ModernHEALTH Specialty Ad-Rx, LLC issued and authorized the checks of employees, including **Relator Edwin Gvalevech**, at the Ad-Rx Los Angeles, California branch.

26. **ModernHEALTH**, a portfolio company of private equity firm Altamont Capital Partners, Inc., was formed through the acquisition of other specialty pharmacies and operates several specialty pharmacies throughout the country for several distinct patient populations, including patients with HIV, autoimmune diseases, cystic fibrosis, and hepatitis C. Each of these pharmacies are now branches of Kroger Specialty Pharmacy, including Relator's HIV-focused Los Angeles, California pharmacy.

27. **ModernHEALTH** submits claims for payment of prescription medications to California ADAP, California's Medicaid Program ("MediCal"), and Medicare Part D, and as part of its submission expressly and impliedly certifies that it has complied with the state and Federal regulations as a condition of payment.

28. All acts alleged herein attributed to **ModernHEALTH** have been committed by **ModernHEALTH's** officers, directors, employees, representatives or agents who at all times acted on behalf of ModernHEALTH and within the course and scope of their employment.

C. Defendant Clinics and Providers

29. **ERL Medical Corporation d/b/a LimKeith Multispecialty Medical Clinic, Inc., "LimKeith,"** is a California closely held corporation with its principal place of business at 6200 Wilshire Boulevard Suite 1510, Los Angeles, California 90048. The clinic is a general medical practice with a special focus on the treatment of HIV AIDS and provides pain management services as well as urology, psychiatric, psychological, chiropractic, urgent care,

minor surgery, and infusions therapy services. **LimKeith**'s president and registered agent is **Emmanuel R. Lim** at 2424 Glendower Avenue, Los Angeles California 90027.

30. **Emmanuel R. Lim, MD** is the founder, majority owner, and Medical Director of **LimKeith**, located at 6200 Wilshire Boulevard, Suite 1510, Los Angeles, California 90048. He is a licensed physician in the State of California and a family medicine specialist. He is a resident of Los Angeles, California. He regularly writes prescriptions that are filled by **ModernHEALTH**, the majority of which are for CSA Schedule II drugs and specialty AIDS medication.

31. **Douglas Davies, MD** is a neurologist and partner at **LimKeith** located at 6200 Wilshire Boulevard, Suite 1510, Los Angeles, California 90048. He is a licensed physician in the State of California. He regularly writes prescriptions that are filled by **ModernHEALTH**, the majority of which are for CSA Schedule II drugs and specialty AIDS medication.

32. **The Doctor Health Center, Inc. d/b/a "the doctor"** is a closely held corporation with a principal place of business located at 7531 Santa Monica Boulevard, Suite 101A, West Hollywood, California 90046. The Health Center is an HIV specialty clinic founded and operated in the name of **Louis Flores, MD**, a family medicine practitioner whose clinic is operated by his son, William Flores, a licensed Physician's Assistant. Its registered agent is Maxim Tselevich, located at 7531 Santa Monica Boulevard, Suite 101A, West Hollywood, California 90046.

IV. JURISDICTION AND VENUE

33. Subject matter jurisdiction lies in this Court pursuant to 28 U.S.C. §§1331, 1345, and 1355.

34. The Court may exercise personal jurisdiction over **ModernHEALTH** pursuant to 28 U.S.C. §1391 (b)-(c) and 31 U.S.C. § 3732, which specifically confers jurisdiction for actions brought pursuant to 31 U.S.C. § 3730.

35. Venue is proper in the Federal District Court, Central District of California because Defendant specialty pharmacy **ModernHEALTH**; Defendant clinics **ERL Medical Corporation** and **The Doctor Health Center, Inc**; and Defendant Prescribers **Emmanuel R. Lim, MD**, **Douglas Davies, MD**, and **Louis Flores, MD** transact business in this District, including the filling and writing of prescriptions, respectively, and caused false claims to be submitted in this judicial district in violation of 31 U.S.C. §3729.

36. Before filing this action, Relator informed the DEA of Defendant **ModernHEALTH**'s scheme to receive payment for false claims submitted for CSA Schedule II drugs dispensed by **ModernHEALTH** and prescribed by **Defendant Prescribers** and other physicians in violation of the requirements of the CSA.

37. Before filing this action, **Relator** provided written notice to the United States Department of Justice and **Relator** also provided Disclosure Materials to the United States Attorney General, the United States Attorney's Office for the Central District of California, Western Division, and to the Attorney General of the State of California.

V. LEGAL AUTHORITY

A. False Claims Act

38. The False Claims Act provides, in part, that any entity that (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or

fraudulent claim, is liable to the United States for damages and penalties. 31 U.S.C. §§ 3729(a)(1)-(2), as amended by 31 U.S.C. §§ 3729(a)(1)(A)-(B).

39. To show that an entity acted “knowingly” under the False Claims Act, requires proof that the entity, with respect to information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. Proof is not required to show that an entity had the specific intent to defraud the United States. 31 U.S.C. § 3729(b), as amended by 31 U.S.C. § 3729(b)(1).

B. Payment of Claims under Medicare Part D

40. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, established the Health Insurance for the Aged and Disabled Program, commonly referred to as “Medicare.” Pursuant to the Medicare program and other government healthcare programs described below, the government pays claims for reasonable and necessary healthcare provided to its beneficiaries.

41. Medicare has multiple parts:

- Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services, hospice services and related care.
- Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of physicians' services and outpatient diagnostic tests.
- Medicare Part C, the Medicare Advantage program, covers both Part B and C and can cover additional services through plans administered by private insurance companies.

- Medicare Part D, the Medicare Prescription Drug Benefit, covers the costs of prescription drugs and is also available as part of Part C Medicare Advantage plans.

42. The Medicare prescription drug benefits program known as Medicare Part D became effective January 1, 2006. 42 U.S.C. § 1395w-101(a)(2).

43. When a pharmacy such as **ModernHEALTH** dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives payment from the Part D Plan Sponsor for the costs not paid by the beneficiary.

44. **ModernHEALTH**, as a contract provider for a Part D Plan Sponsor, is required to comply with all applicable federal laws, regulations, and CMS instructions, which include the CSA, the Social Security Act, and regulations that define the requirements of a valid prescription. 42 C.F.R. § 423.505(i)(4)(vi).

45. **ModernHEALTH** also expressly "agrees to comply with Federal laws and regulations designed to prevent fraud, waste and abuse, including, but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act, 32 U.S.C. §§ 2729 et seq. 42 C.F.R. 423.505 (h)(1). Under Medicare part D, CMS will only pay for drugs dispensed with a valid prescription. 42 U.S.C. §1395w-102(e).

46. **ModernHEALTH**, as a contract provider for a Part D Plan Sponsor, is also required to comply with all applicable state standards as part of its contractual agreement. 42 C.F.R. § 423.504(b)(iv)(A).

47. **ModernHEALTH**, as a contract provider for a Part D Plan Sponsor, is further required to certify that the claims data it submits to the government agencies is accurate, complete,

and truthful and it must acknowledge that the claims data will be used for the purpose of obtaining government payments. 42 C.F.R. 423.505 (k)(3).

48. **ModernHEALTH**, as a contract provider for a Part D Plan Sponsor, sends CMS data to support its claims for government payment on a Prescription Drug Event (“PDE”) record, which includes the drug dispensed, prescription, payment to the pharmacy, and the provider who ordered the medication, including the provider’s unique identifying number assigned by the licensing State.

49. Compliance with the requirement that such PDE data is “true, accurate, and complete” is *a condition of payment* under the Medicare Part D program.

50. PDEs submitted to Medicare for controlled substances dispensed without a valid prescription in violation of the CSA do not contain accurate, complete, and truthful information about all data related to payment and are thus false claims for payment.

51. Valid prescriptions must be personally written or authorized by a licensed provider authorized to determine appropriate medication and dosage. The provider must then sign the prescription or order stating the quantity and directions for use. While an emergency supply may be dispensed before the signed written prescription is received, federal law requires a written prescription meeting the requirements to be ultimately provided within seven (7) days if the controlled substance is classified as Schedule II. 21 C.F.R. §1306.11(d).

52. As a result of Defendants’ fraudulent scheme, CMS has made payments to **ModernHEALTH** for Part D claims based on illegally prescribed and dispensed prescription drugs, including controlled substances.

C. Laws and Regulations Governing Dispensing of Dangerous CSA Schedule II Controlled Substances.

53. The Controlled Substances Act (“CSA”) establishes controls over all stages of the chain of distribution of Schedule II drugs in the United States, and over practitioners and pharmacies, through a closed and monitored system which makes it unlawful to manufacture, distribute, dispense, or possess any controlled substance except as authorized by the CSA.

21 U.S.C. § 801 *et seq.*

54. Controlled substances are organized into Schedules I through V according to the characteristics of each substance: drugs included in Schedule I have the greatest potential for abuse, no legitimate medical use, and are illegal. Drugs included in Schedule V have legitimate medical uses and little danger to patients. 21 U.S.C. § 812.

55. Schedule II drugs are dangerous and have a high potential for abuse, but also have a currently accepted medical use and are thus legal, but highly controlled and restricted. 21 U.S.C. § 812(b)(2). Likewise, Schedule III and IV drugs have an accepted medical use with a lower potential for abuse than Schedule I and II drugs. 21 U.S.C. § 812(b)(3)-(4).

56. Under the CSA, a practitioner is a physician, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Pharmacists and Pharmacies are specifically excluded. 21 C.F.R. § 1300.01(b)(7).

57. The CSA prohibits any manufacturer, distributor, or dispenser, including a pharmacy, from distributing or dispensing a controlled substance without a valid prescription. 21 U.S.C. § 829(a) and (b). For Schedule II drugs, the CSA requires that the prescription be in writing, except that a practitioner may give an oral prescription in an emergency situation. 21 U.S.C. § 829(a).

58. All prescriptions for controlled substances shall be

- dated as of, and signed on, the day when issued;
- bear the full name and address of the patient;
- bear the drug name, strength, dosage form, quantity prescribed and directions for use; and
- bear the name, address and registration number of the practitioner.

21 C.F.R. § 1306.05.

59. For Schedule II controlled substances, the dispensing pharmacy must have an original written prescription signed by the practitioner or, in an emergency situation, an oral prescription from the practitioner prior to dispensing the drug. 21 C.F.R. § 1306.11(a) and (d). For nursing home residents, a valid prescription that is transmitted via facsimile to the pharmacy serves as the original written prescription. 21 C.F.R. § 1306.11(f).

60. Under the CSA, no prescription for a Schedule II controlled substance may be refilled. A new prescription is required for each dispense. 21 U.S.C. § 829(a).

61. In the case of an emergency situation, a pharmacist may dispense a CSA Schedule II drug upon receiving oral authorization from a prescribing practitioner, C.F.R. § 1306.11(d), but only if:

- a. The oral prescription must be from the prescribing individual practitioner;
- b. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during only the emergency period;
- c. The pharmacist shall immediately reduce the prescription to a writing that meets the requirements of 21 C.F.R. § 1306.05, except for the signature of the prescribing individual practitioner; and
- d. The pharmacy must receive a written prescription from the prescribing individual practitioner within seven (7) days of the oral prescription.

62. An “emergency” is a situation in which the practitioner determines that immediate administration of a controlled substance is necessary for proper medical treatment and there are no appropriate alternative treatments available. 21 C.F.R. § 290.10.

63. Each element of a valid Schedule II drug prescription must be specified by the prescribing practitioner personally and may not be delegated to an employee or other agent of the practitioner. 75 Fed. Reg. 61,613, 61,614 (Oct. 6, 2010).

64. In California, prescriptions for Schedule II drugs are valid only for six months. Cal. Health & Saf. Code § 11166.

65. Every state, including the **State of California**, requires a written or electronic prescription before dispensing CSA Schedule II drugs in non-emergency conditions.

66. Under the California CSA at CHSC § 11153:

A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

Except as authorized by this division, the following are not legal prescriptions:

- (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or
- (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled

substances, sufficient to keep him or her comfortable by maintaining customary use.

D. Payments Eligible for Payment under State-Funded Medicaid and ADAP Programs.

67. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, establishes Medicaid, a means-tested joint federal-state program that provides healthcare benefits for certain groups, primarily the poor and disabled. Pursuant to the Medicaid program and other government healthcare programs described below, the government pays claims for healthcare provided to its beneficiaries.

68. The California Medicaid program, MediCal, is a comprehensive health insurance program available to certain low-income California residents. MediCal is jointly financed by the State of California and the federal government and administered by the California Department of Health Care Services (“DHCS”).

69. A licensed provider of healthcare services may submit claims for payment for prescription medications, including HIV medication and controlled substances, to beneficiaries to the State's Medicaid program, which in turn is reimbursed in part by the federal government.

70. The percentage of the State's Medicaid obligation paid by the federal government is determined by the Federal Medical Assistance Percentage (“FMAP”) set by CMS, pursuant to 42 CFR 430 and 42 CFR 447. The FMAP for California in the United States' 2016 fiscal year was fifty percent. Office of the Assistant Secretary for Planning & Evaluation, U.S. Dep't of Health & Human Services, “FMAP 2016 Report,” Nov. 2014, *available at* <https://aspe.hhs.gov/basic-report/fy2016-federal-medical-assistance-percentages>; 79 Fed. Reg. 3385, 3385-388 (Jan. 21, 2014).

1. Claims Submission under California's Medicaid Program.

71. MediCal pays healthcare providers for the costs of providing covered health services to Medicare beneficiaries. 42 U.S.C. § 1396x(v)(1)(A). The State programs and the federal reimbursements they receive are regulated by CMS.

72. The infrastructure of MediCal's claims submission process mirrors that established by the Federal government for Medicare. CMS, Medicare-Medicaid Coordination, <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-MedicaidCoordination.html> [accessed August 6, 2016].

73. For example, retail pharmacies must submit an electronic or hard-copy claim form, *CMS 1500*, to the appropriate MediCal carrier. These forms require the provider to submit specified information including the provider, patient, prescribing provider, service(s) provided specified by procedure code, the related diagnosis code(s), dates of service, and amount charged.

74. Pursuant to 42 C.F.R. § 455.18, to obtain payment, providers must certify on each claim form:

(1) *"This is to certify that the foregoing information is true, accurate, and complete."*

(2) *"I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws."*

75. In addition, each Medicaid provider must sign a Provider Agreement confirming their commitment to comply with all Medicaid requirements including the fraud and abuse provisions.

2. Payment of Claims Under California's AIDS Drug Assistance Program (ADAP).

76. Under Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (“RWHAP”), the United States government provides grants to States to improve the quality, availability, and organization of HIV healthcare and support for people living with HIV who have no health insurance, public or private, have insufficient health care coverage, or lack financial resources to obtain the care they need. 42 U.S.C. ch. 6a, subch. XXIV § 300ff *et seq.*

77. RWHAP Part B grants include the AIDS Drug Assistance Program (“ADAP”) awards for the provision of FDA-approved HIV treatment drugs to low income patients. The grants are administered by the United States Department of Health and Human Services (“HHS”) and the Health Resources and Services Administration (“HRSA”). Each State administers a unique AIDS Drug Assistance Program.

78. As federally funded programs, ADAPs are required to acquire drugs “in the most economical manner feasible.” 42 CFR Part 50, Subpart E. The 340B Drug Pricing Program is a federal program administered by HRSA’s Office of Pharmacy Affairs (“OPA”) that provides federally-designated entities, such as ADAPs and other RWHAP recipients, with access to discounted medications. HRSA, HIV/AIDS Bureau, *AIDS Drug Assistance Program (ADAP) Manual 2016* [accessed July 25, 2016], available at <http://hab.hrsa.gov/manageyourgrant/adapmanual.pdf>

79. In administering their ADAP programs, States must ensure that patients receive medication therapies consistent with current Federal HIV/AIDS treatment guidelines. State ADAPs must cover at least one drug from each class of HIV antiretroviral medications.

80. Individual states set financial eligibility, covered drugs published in the ADAP “formulary,” and determine what amount and type of state and local funding to contribute.

Funding is also provided by rebates received by ADAP beneficiaries who purchase medications from certain drug manufacturers through a retail pharmacy network.

81. **California's** ADAP program received a \$98,618,573.00 RWHAP Part B grant for fiscal year 2016. The program is administered by the California Department of Health's ("CDH") Office of AIDS and funded with state and local money in addition to the RWHAP grant.

82. Under the California Health & Safety Code § 120955, the CDH sets the payment rates for specific ADAP drugs.

83. California providers who prescribe medication to ADAP eligible patients contract with pharmacies to fill the prescriptions. These pharmacies are referred to as "contracting pharmacies."

84. Under Cal. Health & Safety Code § 120970(a), in order to be eligible for ADAP reimbursement, contracting pharmacies "shall, either directly or through subcontracted pharmacy outlets, obtain and dispense the necessary drugs, in their approved forms according to the program formulary, and shall comply with all applicable provisions of the California Pharmacy Law."

85. Valid prescriptions must be written by a licensed provider authorized to determine appropriate medication and dosage who then signs the prescription stating the quantity and directions for use. While an emergency supply may be dispensed before the writing is obtained, the laws require that a written prescription meeting the requirements be provided within a specified time frame.

86. As a result of **Defendants'** fraudulent scheme, CMS has made payments and other compensation, including, but not limited to, subsidies and risk adjustments, for drugs

dispensed without a valid prescription, taking into account the false or fraudulent Medicaid and ADAP claims.

D. Anti-Kickback Statute.

87. The Medicare and Medicaid Fraud and Abuse Statute, referred to herein as the “Anti-Kickback Statute,” 42 U.S.C. § 1320a-7b(b), was enacted under the Social Security Act in 1977.

88. The Anti-Kickback Statute arose out of Congressional concern that payoffs to those who influence healthcare decisions will result in goods and services being provided that are medically inappropriate, unnecessary, of poor quality, or even harmful to patients.

89. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b).

90. The Anti-Kickback Statute ascribes liability to both sides of an impermissible kickback relationship.

91. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care. Thus, proof of taint is sufficient, without the need to proof the effect of the taint on specific decisions.

92. Claims for payment for services tainted by kickbacks are false pursuant to the False Claims Act. 42 U.S.C. § 1320a-7b(g).

93. Compliance with the Anti-Kickback Statute is a condition of payment for claims administered by physicians for which Medicare or Medicaid reimbursement is sought. Payment practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. Each of the Government Healthcare Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute and with other federal laws governing the provision of healthcare services in the United States.

94. As such, if a provider informs CMS or its agent that it provided services in violation of the Anti-Kickback Statute or another relevant law including off label indications, CMS will not pay tainted claims, regardless of whether they are otherwise reasonable or medically necessary.

95. The Patient Protection and Affordable Care Act (“PPACA”), Public Law No. 111-148, Sec. 6402(g), amended the Anti-Kickback Statute or “Social Security Act,” 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its “anti-kickback” provisions to be enforced under the FCA.

96. The PPACA also amended the Social Security Act’s “intent requirement” to clarify that violations of the Social Security Act’s anti-kickback provisions may occur even if an individual does “not have actual knowledge” or “specific intent to commit a violation.” PPACA, Public Law No. 111-148, Sec. 6402(h).

97. Violation of the Anti-Kickback Statute subjects the violator to liability for exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation, 42 U.S.C. § 1320a-7(b)(7), 1320a-7a(a)(7), in addition to the treble damages and penalties of the False Claims Act.

98. Compliance with the Anti-Kickback Statute is a precondition to participation as a healthcare provider under the Medicare and Medicaid programs as required by the Provider Agreements set forth in forms CMS-855A and CMS-855I.

99. Either pursuant to Provider Agreements, claim forms, or in another appropriate manner, hospitals and physicians who participate in a federal healthcare program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback Statute, in order to obtain payment. 42 C.F.R. § 424.510(d)(3).

100. Any party convicted under the Anti-Kickback Statute must be excluded from federal health care programs for a term of at least five (5) years. 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the Anti-Kickback Statute, the Secretary may exclude that provider from the federal and related state healthcare programs for a discretionary period and may impose administrative sanctions of \$50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

F. Stark Act

101. Statute 42 U.S.C. § 1395nn, commonly referred to as “Stark II,” and its associated regulations, 42 C.F.R. § 350 *et seq.* (collectively, “Stark”), provide that if a physician has a “financial relationship” with an entity, the physician may not make a referral to the entity for the provision of “designated health services,” unless the relationship satisfies the requirements of an exception set forth in Stark.

102. Prior to Stark’s passage, studies had shown that when physicians had financial relationships with hospitals, they referred more patients to such hospitals than they otherwise would have absent such financial relationship. 66 Fed. Reg. 856, 859 (Jan 4, 2001).

103. Stark further provides that an entity may not present or cause to be presented to Medicare a claim for “designated health services” tainted by a prohibited referral. In addition, Medicare is *prohibited* from making payment on any such claim. Both inpatient and outpatient hospital services are “designated health services” under Stark.

104. Compliance with Stark is also a material condition of payment of a claim through Medicare, Medicaid or other government health plan. The statute, 42 U.S.C. § 1395nn(g)(1), prohibits payment for designated health services provided in violation of Stark. The provisions of Stark have been extended to Medicaid pursuant to 42 U.S.C. § 1396b(s).

105. A violation of Stark gives rise to False Claims Act liability.

VI. FACTUAL BACKGROUND

A. Relator

106. **Relator Edwin Gvalevech** is and has been employed by Defendant **ModernHEALTH** as a Pharmacist since September 2015 in **ModernHEALTH’s** Los Angeles, California location in West Hollywood, known as **Ad-Rx Pharmacy**. As a pharmacist in that facility, Relator’s primary responsibility was and is to authorize and oversee the filling of prescriptions for specialty medication, including HIV/AIDS medication, as well as controlled substances and a wide range of other drugs.

107. Relator earned his Doctor of Pharmacy from the University of Michigan’s College of Pharmacy in 2013. He earned a Bachelor of Science degree in biology from University of California-Irvine in 2008.

108. While completing his studies, Relator worked as a Pharmacy Intern for CVS Pharmacy from 2009 to 2012 and as Pharmacist for Walgreens Co. from 2013 to 2015. As part of pharmacy school graduation requirements, Relator completed four (4) years of clinical training in

which he learned to analyze prescriptions and identify drug interactions as well as to evaluate drug dosages and the medical justification for prescriptions.

109. After graduating from University of Michigan's College of Pharmacy in 2013, Relator pursued a career in retail pharmacy where he utilized his clinical skills as well as his pharmacological expertise. Accordingly, Relator worked for Walgreens as a District Pharmacist from 2013 to 2015, during which time he was assigned to "float" to approximately 100 Walgreens pharmacies where he interacted with and observed the practices of hundreds of retail pharmacists.

B. ModernHEALTH's Organization and Procedures

110. Founded in 1976, **ModernHEALTH, Inc.** owned and operated multiple specialty pharmacies in the United States organized into four (4) business segments:

1) TLCRx Pharmacy, with locations in New Orleans, Louisiana, Orlando, Florida and Addison, Texas, primarily providing services to patients in Rheumatology, Dermatology, Hepatitis C and Cystic Fibrosis;

2) Biofusion, based in Torrance, California, serving patients requiring Subcutaneous Immune Globulin ("SCIG") and IV Immune Globulin ("IVIG") for autoimmune and primary immune deficiency diseases; two Home Infusion Pharmacies in Dothan, Alabama and Richardson, Texas;

3) ModernHEALTH Specialty Pharmacy – Rx in Garden Grove, California, which focuses primarily on oncology and other specialty therapies while also serving as an operational hub for ModernHEALTH's West Coast operations.

4) ModernHEALTH Specialty Pharmacy – AdRx in Los Angeles, California, which focuses primarily on HIV and Hepatitis C therapies.

111. A “specialty pharmacy,” as that descriptor is used in the pharmacy industry and defined by the American Pharmacists Association, is a pharmacy that “focuses on high cost, high touch medication therapy for patients with complex disease states [and offers medications that] range from oral to cutting edge injectable and biologic products.” Specialty pharmacies, including **ModernHEALTH**, typically offer regular pharmacy services in addition to specialty drugs and pain medication.

112. Approximately 90% of the controlled substance prescriptions that **ModernHEALTH** fills from its AdRx facility are for beneficiaries of ADAP, MediCal, and/or Medicare. More than half of these patients are HIV positive who obtain prescriptions for expensive HIV medications as well as large amounts of powerful Schedule II narcotics, the most common of which is oxycodone 30 milligram tablets.

113. On September 2, 2016, **ModernHEALTH** was acquired in a merger with Axiom Pharmacy Holdings, Inc. (“Axiom”), a specialty pharmacy headquartered in Lake Mary, Florida. Axiom was a wholly-owned subsidiary of Kroger. Post-merger, the former Axiom ModernHEALTH pharmacies, including Relator’s California Pharmacy, Ad-Rx, became part of **Kroger Specialty Pharmacy, Inc.**, a wholly-owned subsidiary of Kroger Company, also headquartered in Lake Mary, Florida at the same address as Axiom’s headquarters, and doing business as “Kroger Specialty Pharmacy.”

114. Nationwide, **ModernHEALTH** employs approximately 500 people, including in its former corporate headquarters in Orlando, Florida and in its various dispensing facilities.

115. **ModernHEALTH’s** Chief Executive Officer Dom Meffe, Chief Operating Officer Tom Dervin, and Chief Administrative Officer Joan Schuckenbrock retained their respective positions following the merger and are responsible for ensuring Defendants’ compliance with

applicable laws and regulations. From no later than 2012 until August 2016, Brenda Goodman, served as Senior Vice President of **ModernHEALTH**'s Specialty Pharmacy Division and was chiefly responsible for the division's sales and marketing in addition to pharmacy operations.

116. In September, 2016, Goodman was transferred out of the AdRx facility, stripped of her pharmacy operations duties, and made a Senior Vice President of **Kroger Specialty Pharmacy**, with duties related strictly to sales. In an on-site staff meeting on August 18, 2016, Chief Operating Officer Tom Dervin explained the reason for Goodman's involuntary transfer as a "conflict of interest" with a physician's office.

117. Defendant **Kroger Specialty Pharmacy f/k/a ModernHEALTH** (referred to herein as "**ModernHEALTH**" except where otherwise designated) sells medications, including controlled substances and HIV treatments; provides pharmacy consulting and other services to its customers; and employs pharmacists to provide these services and apply their pharmacological expertise to clinically assess the prescriptions presented.

118. In each of its retail pharmacies, **ModernHEALTH** employs a Pharmacist-in-Charge ("PIC") who is responsible under the **State of California's** "Pharmacy Law" (Cal. Admin. Code tit. 16, s 1709.1) for ensuring compliance with all laws governing the pharmacy's operations. The PIC at **Relator's** West Hollywood location is Ramona Edery.

119. **ModernHEALTH** also employs Pharmacy Technicians and Clerks to process its drug orders and it contracts with vendors for the delivery of medications and other products to the facilities under contract with **ModernHEALTH**. Pharmacy Technicians make up the majority of **ModernHEALTH's** workforce. For example, **Relator's** facility employs six (6) Pharmacists, but more than twelve (12) Pharmacy Technicians.

VII. FRAUDULENT CONDUCT

A. Defendant Physicians Prescribe Unreasonable and Medically Unnecessary CSA Schedule II-V Drugs and ModernHEALTH Dispenses and Submits Claims to the Government in Violation of its “Corresponding Responsibility.”

120. During all relevant times, **ModernHEALTH** maintained a working culture, environment, and practices enabling wide-spread fraud in the dispensing of its CSA Schedule II through V controlled drugs.

121. Further, during all relevant times, **ModernHEALTH** maintained a practice of inadequate or improper employee training and orientation coupled with a lack of appropriate policies and procedures concerning controlled substance regulation.

122. At the same time, **ModernHEALTH’s** management systematically directed its Pharmacists to violate compliance requirements governing the dispensing of CSA Schedule II drugs and, in turn **ModernHEALTH** rewarded management with large quarterly bonuses based on the value and volume of drugs dispensed and/or new patient referrals.

123. Through this combination of carrots and sticks, **ModernHealth** furthered its scheme by causing its employees to commit regular and repeated violations of legal requirements governing the handling and dispensing of controlled substances and to submit false claims to the **United States of America** and the **State of California** for payment of CSA Schedule II drugs which it illegally dispensed, all for the purpose of billing the government for unreasonable and medically unnecessary controlled drugs that were illegally prescribed and/or dispensed.

124. With full knowledge or wanton disregard for the knowledge that a significant portion of its CSA Schedule II potentially dangerous drugs were illegally dispensed, **ModernHEALTH** nevertheless demanded that the **United States** and **State of California** pay for such illegally dispensed and/or unreasonable or medically unnecessary drugs.

125. Based upon his informed experience with Defendants, Relator estimates that AdRx, the West Hollywood **ModernHEALTH** facility where he works, filled and continues to fill between 500 and 700 prescriptions per day.

126. Of those prescriptions, **Relator** estimates that nearly half were prescriptions for CSA controlled substances, 20-30% of which were and are for Schedule II narcotics, most prominently the maximum strength 30mg oxycodone dosage, “oxy30,” a highly marketable street drug. The remaining 70-80% are Schedule III – IV, including Xanax, another commonly abused and diverted drug.

B. LimKeith and The Doctor Health Center Issue Unreasonable and Medically Unnecessary Prescriptions to Increase their Patient Populations, Including Patients Who Travel Long Distances and Expect Such Prescriptions and Whose Prescriptions are Exclusively Filled by ModernHEALTH.

127. Like any pharmacy, **ModernHEALTH** fills prescriptions for an array of prescribers, but serves as the primary pharmacy for certain clinics due to location, the doctor’s specialty, and the relationship between the prescriber and the pharmacy.

128. Because of its status as a specialty pharmacy carrying HIV/AIDS medication, **ModernHEALTH** has a particularly close relationship with providers and their clinics who serve the HIV/AIDS community. **LimKeith** and **The Doctor Health Center** are two such clinics.

129. **LimKeith** relied exclusively on **ModernHEALTH** to fill all of its AIDS medication prescriptions and its CSA Schedule II prescriptions. Only after Relator’s repeated attempts to stop false claims involving filling **LimKeith’s** prescriptions, including his complaints, suggestions, stated refusal to fill prescriptions, and reports to the DEA regarding the lack of medical necessity of **LimKeith’s** controlled substance prescriptions, did Defendant

ModernHEALTH in late August of 2016 cease filling CSA Schedule II drugs prescriptions for Defendant doctors **Lim** and **Davies**, of Defendant clinic **LimKeith**.

130. However, Defendant **Kroger** f/k/a **ModernHEALTH** continues to fill **Dr. Lim's** lucrative prescriptions for expensive HIV medications. Even without the significant volume of controlled substances prescribed by **Dr. Lim**, this informal exclusivity arrangement with **LimKeith** alone is still worth millions of dollars in annual revenue to Defendant **Kroger** f/k/a **ModernHEALTH** due to both the volume of prescriptions filled and the large profit margin on some of the costly specialty AIDS drugs.

131. For example, **Dr. Lim** prescribed \$11.5 million worth of Medicare Part D funded retail medications in 2014 according to public data collected by non-profit news organization Pro Publica. Pro Publica, "Prescriber Checkup, available at <https://projects.propublica.org/checkup/providers/1275514234> [accessed February 2, 2017], the highest of the 7,228 family medicine prescribers analyzed.

132. Similarly, Defendant provider **Louis Flores, M.D.** of Defendant clinic, **The Doctor Health Center, Inc.**, stopped regularly referring his medically unnecessary controlled substance prescriptions to **ModernHEALTH** in late August of 2016 as a result of the concerns raised by **Relator** as part of his attempts to stop false claims.

133. For example, **LimKeith** refers patients with prescriptions for some of the most expensive drugs in the world, such as Harvoni ®, a Hepatitis C drug sold by manufacturer Gilead Sciences, Inc. at approximately \$94,000 for a 12-week prescription. Specialty pharmacies like **ModernHEALTH** earn as much as \$2,600 to \$3,100 in profit per patient per prescription when dispensing these drugs, according to an article by Dr. Adam J. Fein of Pembroke Consulting, Inc., Drug Channels, "How PBMs Profit from the Hepatitis C Formulary Wars...And What It Means

for Specialty's Future," (Jan. 8, 2015), <http://www.drugchannels.net/2015/01/how-pbms-profit-from-hepatitis-c.html>.

134. In order to attract and retain patients who need these expensive specialty drugs, **Defendant Prescribers**, through their **Defendant Clinics**, and **Defendant ModernHEALTH**, until late August 2016, respectively prescribe and dispense opiates that many such patients seek, but are not reasonable or medically necessary. **Defendant Prescribers** profit by becoming the provider of not only the patients' narcotics but also the patients' entire AIDS treatment, while **Defendant ModernHEALTH** profited from the increased revenue from dispensed drug sales.

135. **ModernHEALTH** in turn tied its drug sales results directly to quarterly bonuses for Pharmacist-In-Charge Ramona Ederly and Vice President of Sales Brenda Goodman and Tracey Cumberland.

136. To fraudulently enhance their payments from the government, **Defendant Prescribers** and the **Defendant ModernHEALTH** seized on the confluence of two of today's most pressing public health crises: the AIDS epidemic and the opioid epidemic.

137. According to the National Institute on Drug Abuse, part of the National Institutes of Health, approximately one (1) out of every (3) persons with HIV has a substance abuse problem and (1) out of every (6) is a current or former intravenous drug user ("IDU"). See "Drug and Alcohol Abuse – A Significant Risk Factor for HIV, April 2015," [accessed January 3, 2017], <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/drug-alcohol-use-significant-risk-factor-hiv>.

138. Rather than referring patients to addiction or pain management specialists, **Defendant Prescribers** and **ModernHEALTH** fed their patients' opioid addiction in order to

ensure that the patients continue to return to Defendants for the lucrative provision of the patients' HIV treatment and medications to fraudulently enhance revenue at the government's expense.

139. **LimKeith** was formed when Defendant **Emmanuel Lim, M.D.**, purchased the practice from Paul E. Keith in 1991. The clinic is a general medicine practice with a special focus on the treatment of HIV/AIDS and provides pain management, urology, psychiatric, psychological, chiropractic, urgent care, minor surgery, and infusion therapy services. These services are provided by six (6) affiliated providers, including **Drs. Lim and Davies**, John Kowalczyk, DO, a urologist; Amor Del Mundo, M.D., psychiatrist; psychologist Johanna Schor; and Chiropractor Jess Yuson.

140. As Family Medicine and Neurology doctors respectively, **Drs. Lim and Davies** may prescribe CSA Schedule II drugs. However, they are prohibited from prescribing CSA Schedule II drugs to current or former drug addicts, because **LimKeith** is not registered with the DEA as a Narcotic Treatment Program, a required condition of such prescribing.

141. Once **LimKeith** hired **Dr. Davies**, though, **Dr. Lim** could divide the growing number of CSA Schedule II narcotic prescriptions with another provider in an attempt to stave off suspicion as an identifiable outlier prescriber.

142. **Dr. Lim** prescribes CSA Schedule II drugs far more often than his peers. For example, 28% of **Dr. Lim's** prescriptions are for CSA Schedule II drugs, compared to an average of 3% amongst his peers.

143. **Relator** estimates that 79% of all tablet prescriptions written by **Dr. Davies** and filled by **ModernHEALTH** are for oxycodone for patients who have no history of having tried and failed any "first line" non-controlled, neuropathic pain treatments, such as Neurontin, generically gabapentin, and Elavil, generically amitriptyline, or less dangerous/addictive CSA

Schedule V medications, such as Lyrica, generically pregablin, all relatively common, popular, effective and far less dangerous and addictive treatments for the type of neuropathic pain associated with HIV/AIDS with a low risk of dependency.

C. Defendant ModernHEALTH Maintains a Practice of Dispensing Large Volumes of CSA Schedule II Drugs to Beneficiaries via Invalid or Red-Flagged Prescriptions from Defendant Prescribers and its Other Closely Affiliated Prescribers without Regard to its “Corresponding Responsibility” Not to Dispense Such Drugs Unless Medically Necessary.

144. Under the CSA and DEA’s implementing regulations, prescriptions for CSA controlled substances are only legal and billable to the government if they are “issued for a legitimate medical purpose.” Contracting pharmacies such as **ModernHEALTH** have a “corresponding responsibility” and are prohibited from dispensing such prescriptions unless there is a “legitimate medical purpose.” 21 C.F.R. § 1306.04.

145. The DEA, in conjunction with the California State Board of Pharmacy, has identified numerous “red flags” that pharmacists are legally required to monitor:

- Irregularities on the face of the prescription itself
- Nervous patient demeanor
- Multiple patients with the same address
- Multiple prescribers for the same patient for duplicative therapy
- Cash payments
- Request for early refills of prescriptions
- Prescriptions written for an unusually large quantity of drugs
- Prescriptions written for duplicative drug therapy
- Initial prescriptions written for strong opiates

- Long distances from the patient's home to the prescriber's office
- Prescriptions written outside of the prescriber's medical specialty

146. The California Board of Pharmacy requires that pharmacies exercise their “corresponding responsibility” by monitoring such red flags. When faced with even one of the referenced red flags, a California pharmacist “**must not fill the prescription** when the results of a **reasonable inquiry** do not overcome concern about a prescription being written for a legitimate medical purpose.” *In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran*, Board of Pharmacy Case No. 3802; OAH No. 2011010644; Precedential Decision No. 2013-01.

147. In the course of his employment at **ModernHEALTH**, **Relator** has observed one or more of the referenced “red flags” in connection with thousands of prescriptions from several prescribing physicians.

148. When **Relator** voiced concerns to upper level management, including Vice President of Sales Brenda Goodman, or requested the opportunity to engage in a “reasonable inquiry” from his Pharmacist-in-Charge, Ramona Edery, he was reprimanded by both Goodman and Edery, as described in detail below, and he was directed to forgo such inquiry lest he jeopardize the lucrative flow of prescriptions from the doctor in question to **ModernHEALTH**.

D. Operating in Partnership, Defendants have Prescribed, Dispensed and Billed to the Government Thousands of CSA Schedule II and Other Prescriptions to Government Beneficiaries.

149. **Relator** observed a particularly alarming and repeated pattern of defined “red flags” in the CSA Schedule II prescriptions of several doctors, particularly those practicing in a building adjacent to the West Hollywood **ModernHEALTH** facility where **Relator** works: Defendant **Drs. Lim** and **Davies** of Defendant clinic **LimKeith**.

150. **Drs. Lim and Davies** regularly prescribe 90 or more “oxy30” tablets—the most commonly abused, strongest dose, fast-acting narcotics on the market. A single “oxy30” tablet has a “street” value of between \$30 and \$50 per tablet.

151. A representative sample of specific beneficiaries who had blatantly excessive, unreasonable, and medically unnecessary controlled substance prescriptions or otherwise illegal prescriptions written by **Defendant Prescribers** and knowingly filled by Defendant **ModernHEALTH** in violation of the “corresponding responsibility” of a pharmacy in order to ensure both that (1) Defendant prescribers **retained the multi-million-dollar business** of being the patients’ HIV treating physician (2) while **ModernHEALTH**, in turn, **retained the multi-million-dollar business** of selling the expensive HIV medications of the patients referred by Defendant Prescribers are described below.

152. Both **ModernHEALTH** and the **Defendant Prescribers** fraudulently caused such dispensed drugs to be billed to and paid by the government as false claims.

153. On July 1, 2015 **Dr. Lim** prescribed **Beneficiary B.R.** #90 tablets of 30mg oxycodone, “oxy30.” This was followed on August 1, 2015 by prescriptions for 90 tablets of 2mg, maximum strength, Xanax and promethazine with codeine prescribed by **Dr. Davies**. **ModernHEALTH** Pharmacist-in-Charge Ramona Edery directed a **ModernHEALTH** pharmacist to fill the oxycodone, Xanax, and promethazine prescriptions despite multiple red flags, including lack of step therapy and the medically unnecessary high quantity indicative of drug diversion.

154. **ModernHEALTH**’s motivation to fraudulently dispense the Oxycodone, Xanax, and the promethazine with codeine was motivated by the company’s interest in obtaining the high dollar prescriptions that were part of the exclusivity arrangement between **ModernHEALTH** and

the **Defendant Prescribers. Beneficiary B.R.** was also filling a monthly prescription for the Hepatitis C medication Harvoni, billed to the government at \$30,000 per month. However, once the Harvoni treatment was completed on March 3, 2016 for **Beneficiary B. R.**, Edery declined to fill any of **Beneficiary B.R.**'s prescriptions because she was aware that they were medically unnecessary and absent of the kickback reward of the large dollar drug.

155. On June 20, 2016, William Flores, PA, son of **Louis Flores, M.D.** prescribed **Beneficiary K.B.** #150 Percocet 10/325, which is 10mg oxycodone combined with 325mg acetaminophen. Because **Beneficiary K.B.** had been receiving this same prescription since early 2015 with no step therapy, in early 2016 **Relator** requested additional information regarding **Beneficiary K.B.**'s treatment progress.

156. Thereafter, William Flores began indicating "referred patient to pain management" on the face of each prescription for **Beneficiary K.B.** After months of receiving prescriptions with this indication, a **ModernHEALTH** pharmacist asked **Flores** about the status of the referral and received a responsive letter from **Flores** stating that **Beneficiary K.B.** was under a treatment plan approved by Dr. Bahman Shamloo, a pain management specialist, and was to remain on Percocet under Flores' care for one (1) year. **Relator** contacted Dr. Shamloo and learned that Beneficiary K.B. was not involved in any such treatment plan and that **Dr. Flores'** prescription justification and letter had been fraudulent to obtain the oxycodone for the beneficiary.

157. On June 30, 2016, **Dr. Davies** prescribed **Beneficiary L.S.** #70 30mg oxycodone, "oxy30." Upon reviewing **Beneficiary L.S.**'s history with controlled substances, **Relator** discovered other than two immediately prior "oxy30" prescriptions from **Dr. Davies, Beneficiary L.S.** had not been prescribed any controlled substances in the last year, an alarming fact given that

“oxy30” is the strongest oxycodone dose and because the stated reason for the prescription was “chronic pain.”

158. **Relator** refused to fill the above described prescription for **Beneficiary L.S.** despite Vice President Goodman’s routinely repeated commands that **LimKeith’s** prescriptions be filled *without scrutiny* because of the value of the high volume of patients and prescriptions referred by **LimKeith** to **ModernHEALTH**.

159. On June 2, 2016 **Dr. Lim** prescribed **Beneficiary P.D.**, a former intravenous drug abuser according to medical records observed by **Relator** in the course of his clinical duties, #300 methadone 10mg tablets for 30 days, or approximately 100mg per day. The fact that **Beneficiary P.D.** is a former drug addict taking methadone is a major defined “red flag,” particularly because **Dr. Lim** is not licensed to treat addiction. Additionally, the amount of methadone prescribed is more than double the recommended dosage for pain management, 30-40mgs and more than two to three times the two or three tablets daily **Beneficiary P.D.** told **Relator** she takes.

160. On **June 20, 2016**, **Dr. Lim** prescribed **Beneficiary D.B.** #120 tablets of 30mg oxycodone, “oxy30.” **Relator** refused to fill the prescription because it was not dated.

161. **Relator** sent **Beneficiary D.B.** back to **Dr. Lim**. When **Beneficiary D.B.** returned to **ModernHEALTH**, **Relator** asked him to wait a moment while he requested clarifying information from **Dr. Lim**. **Relator** had noticed that **Beneficiary D.B.** had been taking oxy30 for neuropathy since September 20, 2012 without interruption or step therapy.

162. **Beneficiary D.B.** became very upset about waiting. Alarmed at this exhibition of behavior typical of addicts, **Relator** obtained and reviewed **Beneficiary D.B.’s** chart notes and noticed yet another “red flag”—**Beneficiary D.B.** had failed pain management but not been

referred to a pain specialist. Moreover, **Beneficiary D.B.**'s medical records and CURES report indicated no attempts at step therapy whatsoever.

163. Nevertheless, in furtherance of **ModernHEALTH**'s fraud scheme, its Pharmacist-in-Charge directed **Relator** to fill **Beneficiary D.B.**'s prescription and to cease further questioning or carrying out his "corresponding responsibility."

164. On May 6, 2016, Ali A. Mumtaz, M.D. prescribed #150 30mg tablets of oxycodone "oxy30" to **Beneficiary G.C.** who lives in Lancaster, California, over 70 miles away from the doctor and from **ModernHEALTH**, requiring a nearly two-hour drive each way from his home. Traveling this far for a drug that could undoubtedly be obtained at a pharmacy closer to the beneficiary's residence is a serious "red flag," but **ModernHEALTH**'s Pharmacist-in-Charge required **Relator** to fill the prescription without further inquiry.

165. On July 30, 2015, **Dr. Lim** prescribed **Beneficiary S.D.** #392 800mg tablets of Fentora, generically known as fentanyl lozenges, for 30 days. At various points in 2015 and early 2016, **Lim** also prescribed **Beneficiary S.D.** Dilaudid, a brand of hydromorphone, methadone and fentanyl lozenges, frequently together.

166. When **Relator** contacted **Dr. Lim** on June 12, 2016 regarding the reasonableness and medical necessity of such large quantities of such powerful opioids and his concern about duplicate therapy to prescribe multiple medications for the same pain during the same period, **Dr. Lim** abruptly and without explanation told **Relator** to discontinue the most potent drug, Fentanyl.

167. In an email sent to his superiors, **Relator** indicated that he believed that had he not questioned the validity of the prescription and attempted to stop the false claim, **Beneficiary S.D.** could have died.

168. On May 5, 2016, **Beneficiary J.D.** came to **ModernHEALTH** to pick up his OxyContin 80mg and oxycodone 30mg prescribed by **Dr. Davies**. Upon hearing that **Davies** had doubled the OxyContin dosage, **Beneficiary J.D.** became so worried that the amount was too high that **Relator** and another pharmacist refused to fill the prescription out of concern for possible overdose.

169. Upon inquiry by **Relator**, **Davies** explained that he had doubled the extended release OxyContin dosage because **Relator** had refused to fill an earlier “oxy30” prescription for **J.D.**

170. **Davies** also admitted that he had been out of town at the time the double-dosage OxyContin prescription was “written.” **Relator** reported this incident to his **ModernHEALTH** Pharmacist-in-Charge and to its Vice President Goodman the same day and stated in a May 5, 2016 email to both that he would refuse to fill any more of **Dr. Davies’** prescriptions in light of the fact that the patient “would have been on the floor unable to move or possibly worse” and that “[Davies] could have killed this patient.” Similarly, **Davies** prescribes **J.D.’s** partner **A.H.** the exact same medically unnecessary oxycodone, OxyContin, and Xanax medications

171. On June 18, 2016, **Dr. Lim** prescribed **Beneficiary D.J.** #120 oxycodone 30mg tablets “oxy30” after having already prescribed **Beneficiary D.J.** #120 tramadol 50mg tablets, a weaker CSA Schedule IV opiate, #90 350mg Soma tablets, a CSA Schedule IV muscle relaxant, and #90 2mg tablets of Xanax, a CSA Schedule IV benzodiazepine.

172. First, **Relator** was alarmed about **Dr. Lim’s** prescriptions for **Beneficiary D.J.** because the strongest opiate previously prescribed to **Beneficiary D.J.** was the much weaker Norco 10/325, 10mg hydrocodone combined with 325mg acetaminophen.

173. Second, **Relator** was alarmed by the blatantly duplicate therapy consisting of prescribing two (2) short-acting painkillers, “oxy30,” and Tramadol 50mg, equivalent to a 120-day supply prescribed month after month, while **Beneficiary D.J.** stated he took only one (1) tablet of each daily.

174. Third, **Relator** was concerned about the fact that **Beneficiary D.J.** filled the prescription for the latter drug at a different pharmacy, although it was also prescribed by **Dr. Lim**, another “red flag.”

175. Fourth, **Relator** noted that the multiple prescriptions of drugs constituted the dangerous “trinity cocktail” of oxycodone, Soma, and Xanax, a popular albeit illegal recreational drug pairing that can cause both euphoria and cardiac arrest, but is not medically necessary.

176. Fifth, **Relator** was alarmed by **D.J.’s** angry outburst upon learning that **Relator** would need more information before filling the “oxy30” prescription, calling **Relator** “racist.”

177. Finally, when **Relator** contacted **Dr. Lim** for explanation of this host of issues, **Dr. Lim**, rather than offering an explanation, abruptly changed the “oxy30” prescription from 120 to just 30 tablets. After Dr. Lim transferred his patients from ModernHEALTH to a different pharmacy in August 2016, he one again began prescribing D.J. 120 tablets of oxy30.

178. On June 8, 2016, **Dr. Lim** prescribed **Beneficiary J.B.** #180 oxycodone 30mg “oxy30” tablets. Before filling the prescription, **Relator’s** fellow staff pharmacist, Michael Najarian, alarmed at the sheer quantity of this maximum strength narcotic being prescribed, asked **Dr. Lim** for information regarding the patient’s chart notes, step therapy, pain scale readings, and length of treatment. **Dr. Lim** provided nothing in response; instead he talked directly with Pharmacist-in-Charge Edery who, in turn, screamed at and directed Najarian to fill the prescription

anyway without any additional information and without regard for his “corresponding responsibility.”

179. **Beneficiary C.G.**, whom **ModernHEALTH** Pharmacist-in-Charge Ramona Edery repeatedly described to **Relator** as a “pimp” in the Los Angeles area LGBT community, is regularly prescribed large quantities of the “trinity cocktail” of “oxy30,” Soma, and Xanax by **Dr. Davies** in addition to several consecutive years of Promethazine with Codeine, a commonly abused narcotic cough syrup. On multiple occasions, **Relator** has witnessed **Beneficiary C.G.** “visit” the pharmacy with others and ask what “brand” of Soma and Promethazine the others with him “preferred.”

180. **Relator** is aware that different brands have different street values and some addicts have a particular favorite. Based on his observations, **Relator** raised concerns to **ModernHEALTH’s** Pharmacist-in-charge and its Vice President Goodman about the extremely high likelihood of diversion of **Beneficiary C.G.** prescriptions from **Dr. Davies**, but **ModernHEALTH** continued to dispense and bill the government without questioning these “red flags.”

181. **Beneficiary J.H.** was prescribed 360 +/- 40 oxycodone @ 30mg every 28 days in 2016 by **Dr. Davies**. Both the quantity and frequency of this maximum strength prescription, amounting to approximately nine (9) tablets daily, were serious defined “red flags” as 270 mg of oxycodone in a single day is more than enough to cause respiratory failure, even in a drug dependent beneficiary with a high tolerance.

182. Moreover, despite indication of chronic pain in **Beneficiary J.H.’s** chart, he had not been prescribed any long-acting opioid, and he had previously had his prescriptions filled at West

Aid Pharmacy in Los Angeles, which, on information and belief, was shut down after the California Board of Pharmacy detected alleged illegal narcotic dispensing practices.

183. However, **ModernHEALTH's** Pharmacist-in-Charge, Edery, directed **Relator** to dispense the prescribed drugs to **Beneficiary J.H.** per **Dr. Davies'** prescription.

184. Edery also threatened **Relator** that further protests about dispensing drugs to doctors in the **LimKeith** clinic were prohibited, and that **Relator** would be subject to formal reprimand by Vice President Goodman if he persisted in his hesitations to dispense drugs prescribed by **LimKeith** doctors and attended to his "corresponding responsibility."

185. As a trained retail pharmacist, **Relator** knows that the above oxycodone prescriptions, as well as hundreds of other oxycodone prescriptions **ModernHEALTH** forces him and his colleagues to fill without scrutiny, cannot be medically justified and thus constitute false claims for unreasonable and medically unnecessary drugs dispensed to beneficiaries and billed to the government.

186. According to a recent comprehensive report by the United States Centers for Disease Control ("CDC"), the *CDC Guideline for Prescribing Opioids for Chronic Pain*, prescribers "should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate." The Guideline also highlights the importance of "working with patients to taper and discontinue opioids."

187. Many of the beneficiaries receiving prescriptions from **Defendant Prescribers** and having them filled by **ModernHEALTH** either have a history of drug abuse or addiction, currently abuse drugs, are addicted to drugs, or show signs of addiction. According to the Medical Board of California's Guidelines for Prescribing Controlled Substances, "[i]n patients who are

actively using illicit drugs, the potential benefits of opioid therapy are likely to be outweighed by potential risks.” http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf

188. Since he began working with **ModernHEALTH** in September, 2015, **Relator** has filled and seen his colleagues fill thousands of oxycodone prescriptions, but rarely, if ever, has he seen prescriptions with medical documentation from **Defendant Prescribers** indicating any tapering or that a detailed risk-benefit analysis is being performed.

189. Rather, **Relator** has observed prescription patterns indicating routine, indiscriminate writing of oxycodone and other CSA Schedule II prescriptions for AIDS patients in amounts that far exceed usual therapeutic levels as well as the repeated falsification of medical records and chart notes intended to keep inquisitive, ethical pharmacists like **Relator** “comfortable” as to their “corresponding responsibility” and to deter them from raising concerns about false claims.

190. In or around late April 2015, **Relator** began regularly requesting that **Dr. Lim** and **Dr. Davies** provide additional explanation and documentation supporting their oxycodone 30mg, “oxy30,” prescriptions. In response, **Lim** and **Davies** provided false chart notes or simply did not respond substantively at all.

191. For example, **Dr. Lim** charted that oxycodone patient beneficiaries were experiencing lower back pain at a 10 out of 10 on the clinical pain scale. When **Relator** personally observed such patient beneficiaries in the pharmacy requesting medication, they were either not in pain at all or did not exhibit limited movements or facial expressions associated with a person with a 10/10 pain scale rating, which, according to the Numeric Rating Scale most commonly used for pain ratings, is for patients who indicate that they are in “the worst pain imaginable.” Brievik et al., *Assessment of Pain*, 101 Br. J. Anaesth., 2008, Fig. 1.

192. Additionally, **Relator** reviewed records of patient beneficiaries with “red flag” oxycodone prescriptions on the Controlled Substance Utilization Review and Evaluation System (“CURES”), California’s prescription drug monitoring program. The CURES database allows **Relator** to analyze patient beneficiaries’ drug therapy history, enabling him and other pharmacists to fulfill their “corresponding responsibility” to make determinations regarding the inappropriateness of maximum oxycodone prescriptions or other “red flag” indicators.

193. For example, **Relator** would discover on CURES that prior to receiving a maximum dose of oxycodone, many patient beneficiaries had not received the far less powerful pain medication, such as Lyrica, a CSA Schedule IV non-opiate with low risk of addiction, most commonly used to treat neuropathic pain, the type of pain commonly experienced by AIDS patients.

194. Rather, **Relator** observed that patient beneficiaries of **Drs. Lim and Davies** often were described by those Defendants as having jumped from mild pain medication prescriptions suddenly up to “oxy30,” a clear sign of fraud and abuse, as normal practice would involve prescribing to beneficiaries intermediate painkillers, such as hydrocodone, or smaller amounts and dosages of oxycodone in a progression before prescribing “oxy30.”

195. Finally, in addition to “red flagged” high quantities and dosages; “red flagged” treatment history and duplicate therapy; and fraudulent chart notes and evasive or non-existent verbal explanations from **Defendant Prescribers**, in his attempts to stop false claims, **Relator** has also observed and reported the routine, regular, month-after-month dispensing and billing of prescriptions drugs including for the lethal “Trinity” drug cocktail. Notorious for the euphoria it produces, the combination of Oxycodone or Hydrocodone, Carisoprodol (Soma), and Alprazolam (Xanax) can cause cardiac arrest and is notoriously lethal.

196. Despite **Relator's** repeated attempts to stop false claims perpetrated through the above described schemes by going to **ModernHEALTH's** management, Pharmacist-in-Charge Ramona Edery, Senior Vice President Brenda Goodman, and other members of **ModernHEALTH's** upper management, **Relator** has been unable to stop false claims because **ModernHEALTH** has disregarded its "corresponding responsibility" and instead continued its kickback-driven practice of dispensing dangerous drugs based upon "red flagged" prescriptions from its partner prescribers with no questions asked.

197. **ModernHEALTH** has continued to pressure its Pharmacists to fill dangerous and medically unnecessary prescriptions for oxycodone and other CSA Schedule II drugs by responding to any questioning of "red flags" regarding the validity of such prescriptions with retaliatory verbal reprimands, threats, increased scrutiny of performance in order to find grounds for pretextual written reprimands and bullying and verbal attacks on such Pharmacists' skill and integrity.

E. Defendant ModernHEALTH's Scheme to Fill Illegal Prescriptions in Exchange for Referrals and Kickbacks to and from Defendant Emmanuel Lim, M.D.

198. **ModernHEALTH** has incentivized **Dr. Lim** to use its services and refer patient beneficiaries to have their prescriptions filled at **ModernHEALTH**, by not charging **Dr. Lim** what he owes in copays or cash payments for medications and by filling unreasonable, medically unnecessary and dangerous prescriptions **ModernHEALTH** understands are being diverted or abused.

199. Since at least 2012, **Lim** has been self-prescribing Atripla®, an antiviral medication used to treat HIV, and having his prescriptions filled at Defendant **ModernHEALTH's** pharmacy. **ModernHEALTH** submits claims for **Lim's** Atripla through their Pharmacy Benefit Manager to

his private insurer, Health Net, Inc., which pays approximately \$25,000 per year for a one-year course of treatment, which includes twelve (12) monthly 28-day prescriptions.

200. Atripla is the one of the most lucrative drugs **ModernHEALTH** dispenses and bills to the government.

201. **ModernHEALTH's** Pharmacist-in-Charge, Ramona Edery, authorized the filling of **Dr. Lim's** personal prescriptions, and would often mention, nonchalantly and occasionally as if the fact was humorous, that **Dr. Lim** did not suffer from HIV or post exposure prophylaxis, confirming the kickback scheme between **Dr. Lim** and **LimKeith** on the one hand and **ModernHEALTH** on the other.

202. In addition, **Lim** also prescribes and obtains drugs based on prescriptions for medications with which Atripla is known to interact that can cause serious side effects if taken together.

203. To avoid pharmacists noting "red flags" and questioning the dispense of the expensive and medically unnecessary HIV drugs to **Dr. Lim** personally, **ModernHEALTH's** Pharmacist-in-Charge, Edery, assigned **Lim's** personal prescriptions exclusively to Pharmacist Marjan Adeli and Pharmacy Technician Christel Lopez for filling, because they maintained a practice consistent with **ModernHEALTH's** directives not to question prescriptions or raise concerns about "red flags" in contrast to **Relator** who attempted to stop such false claims.

204. When confronted, the only explanation **ModernHEALTH** Pharmacist-in-Charge Ramona Edery could muster was "maybe he is giving them to his boyfriend."

205. **Dr. Lim** had been receiving Atripla monthly for over five (5) years, a fact Edery initially denied knowing. However, Edery had reviewed and expressly authorized the filling of **Dr. Lim's** Atripla prescriptions. Both Edery and Senior Vice President Goodman had on several

occasions told the pharmacy staff that **Dr. Lim** did not have HIV, but to fill his prescriptions for HIV-related drugs promptly without questioning.

206. When **Relator** refused to fill such prescription for **Dr. Lim**, Edery filled it herself and reported **Relator's** refusal to Salvador A. Scaccia, **ModernHEALTH's** Vice President of Operations.

207. In a January 6, 2017 email to **Relator** and his fellow **ModernHEALTH** Pharmacists, Scaccia reprimanded them and instructed them to:

“be a little careful about patient information and patient status. I think as pharmacists it is not our job to investigate every little detail. If the [prescription] is legitimately written by a MD then we should be able to comfortably fill it. I don't think it's our right to ask him right now if he is positive or not.... But what difference does that make? I think you would be crossing a strong line of discriminating if you call him to ask him that personal information. And remember discrimination is a very strong and powerful word. We don't not always know the health details of all of our patients. You need to put your personally feelings aside and think about this [prescription] only. There is no reason to not fill this [prescription]....”

208. Appalled, **Relator** responded to Scaccia via email, respectfully disagreeing with Scaccia's characterization of **Relator** and other conscientious **ModernHEALTH** Pharmacists fulfilling their “corresponding responsibility” as pharmacists to identify “red flags,” exercise clinical judgment regarding the appropriateness of prescriptions, and follow-up with patients and prescribers, as a form of discrimination. **ModernHEALTH's** Scaccia did not reply.

209. **In addition** to filling **Dr. Lim's** Atripla prescriptions despite knowing that the prescription is unreasonable and not medically necessary, **ModernHEALTH fills thousands of dollars worth of prescriptions for Dr. Lim without charge as part of its kickback scheme.**

210. According to accounts receivable records viewed by **Relator** in the course of reviewing **Dr. Lim's** Atripla prescriptions history, **ModernHEALTH**, through Senior Vice President Brenda Goodman, routinely “zeroes out” the balance owed by **Dr. Lim** for a wide range

of drugs by providing him with a “courtesy adjustment” equal to the amount billed and posted to his Accounts Receivable (“A/R”) account.

211. The **Dr. Lim** “adjustment” is entered as “BD CRTSY ADJ BG”, “BD” indicating that amount has been billed but not paid, and the initials “BG” indicating that Brenda Goodman approved the “adjustment.”

212. A small but representative set of examples of the kickbacks to **Dr. Lim** authorized by Goodman include a \$5,596.53 “adjustment” on February 3, 2014; a \$544.02 “adjustment” on June 30, 2014; and a \$524.87 “adjustment” on March 31, 2015. At all times including the present, **Dr. Lim**’s account has indicated the date of his “Last Payment” as “00/00/00.”

213. The federal Anti-Kickback Statute generally prohibits the exchange or offer to exchange, anything of value, in an effort to induce or reward the referral of federal health care program business. 42 U.S.C. § 1320a-7b.

214. The Stark Law generally prohibits “self-referrals,” or the referral by a physician of a Medicare or Medicaid patient to an entity providing “designated health services” if the physician has a “financial relationship” with the entity.

215. Designated health services include outpatient prescription drugs, 42 C.F.R. § 411.351, and a “financial relationship” includes any compensation arrangement involving “remuneration” of any kind between the physician and entity “directly, indirectly, overtly, or covertly, in cash or in kind.” 42 U.S.C § 1395nn(h)(1)(B).

216. By routinely filling prescriptions for **Dr. Lim** without scrutiny despite knowledge of lack of medical necessity and by giving him medications without charge and waiving his payments due, **ModernHEALTH** sought to induce **Dr. Lim** to continue referring his patients to **ModernHEALTH** to have their prescriptions, including those for expensive HIV medications and

medically unnecessary CSA Schedule II drugs, filled and billed to the government by

ModernHEALTH.

217. In addition to Defendant Lim, Defendant Pharmacy ModernHEALTH maintains like partnership/kickback arrangements involving the manipulation of A/R accounts with numerous other providers including, but not limited to: Mark Honzel, MD; Peter Anton, MD; Kerry Flowers, MD; Michael Gottlieb, MD; Erron Gralore; Eric Lynch, David McDonough, MD; Phillip Musikanth, MD; and Richard Oravec, MD.

F. Defendant ModernHEALTH's Dispensing and Billing of CSA Controlled Substances.

218. In order to further its kickback scheme and to bill the government for knowingly unreasonable and medically unnecessary drugs, **ModernHEALTH** directed its Pharmacists and Pharmacy Technicians to fill "red flagged" prescriptions without scrutiny, even when dispensing CSA Schedule II drugs.

219. Further, **ModernHEALTH** did not routinely or regularly provide training or orientation about dispensing controlled substances to its Pharmacists-in-Charge, who are responsible for overseeing ModernHEALTH's Pharmacists who review and fill the majority of the prescriptions or to its Pharmacy Technicians, who process and submit the claims for payment.

220. **ModernHEALTH** did not accurately record whether it had received provider-signed, dated and otherwise valid prescriptions for controlled substance orders, as required by the state and federal law and regulations described above.

221. For at least two (2) years prior to **Relator** commencing employment with **ModernHEALTH** in September 2015 and continuing during his employment through the present, **ModernHEALTH's** AdRx facility dispensed and billed the government for (1) CSA Schedule II

drugs in response to prescriptions dated and or signed by someone other than the prescriber outside of the prescriber's presence; (2) prescription drugs dispensed pursuant to falsified prescription records used to circumvent limits on the number of refills allowed by law under the ADAP program; (3) generic drugs pursuant to falsified refills request forms; and (4) expensive HIV and other medications pursuant to falsified prior authorization forms.

222. **ModernHEALTH** stressed productivity requirements to obtain and fill drug orders as priorities for its pharmacy workers' employment and it incentivized its management with quarterly bonuses to demand that its Pharmacists dispense without scrutiny. Pharmacist-in-Charge Ramona Edery, as well as Sales executives Brenda Goodman and Tracey Cumberland, receive quarterly productivity bonuses based in whole or in part on gross sales and/or gross receipts of dispensed drugs and products.

223. **ModernHEALTH's** then-Vice President of Specialty Pharmacy Brenda Goodman repeatedly expressly stated that productivity and retaining prescribing doctors' referrals whose prescriptions provide large amounts of revenue outweighs concerns with regulatory compliance.

224. On May 19, 2016, in response to **Relator's** verbal expression of concern about the validity of an oxycodone prescription written by Defendant **Dr. Davies, Lim's** partner, Goodman impugned **Relator's** competency and threatened his job, stating "you wish you were a doctor don't you...do you really think we will need four pharmacists here if we lose **Dr. Lim?**"

225. When **ModernHEALTH** receives orders for CSA controlled substances, its Pharmacy Technicians electronically enter the information into the QS/1 NRx software application. A staff Pharmacist then verifies the accuracy of the entered data, and the software automatically assigns a prescription number. The Pharmacy Technician then sends the claims to

the Pharmacy Benefits Manager who processes the claim to the payor, most typically a managed care organization who contracts with State MediCal, ADAP programs, and Medicare Part D.

226. **ModernHEALTH**'s corporate offices, including its Chief Operating Officer Thomas Dervin and Chief Administrative Office Joan Schuckenbrock, are aware, following written and oral correspondence from **Relator** between April and September of 2016, of the practices that constituted and caused the myriad violations of the CSA that occurred at the AdRx facility.

227. Nevertheless, Dervin and Schuckenbrock condoned and encouraged such practices and then reluctantly made changes only after several months of **Relator's** complaints and reports. They continued to encourage such conduct by paying productivity bonuses to Edery and Goodman and by refusing to take the actions necessary to be in compliance.

228. Indeed, **ModernHEALTH's** conduct carried out its mantra stated by Goodman that revenues obtained through false claims take priority over compliance.

1. Defendant ModernHEALTH's Filling of Prescriptions for Schedule II Drugs Illegally Signed and Dated by Defendants LimKeith, Dr. Lim, and Dr. Davies.

229. Under 21 C.F.R. § 1306.05, prescriptions for controlled substances must be signed by the prescriber or his/her authorized agent on the same day the prescription is written. California law is stricter, as prescribers must sign *and* date their prescriptions. CHSC § 11164(a)(1).

230. In early May 2015, **Relator** began noticing clear differences in the handwriting on prescriptions for CSA controlled substances ostensibly written by the same doctor. After calling the office of one of the physicians, **Emmanuel Lim, MD**, **Relator** was told by "Raquel" in **Lim's**

office that she signed and dated prescriptions including those for CSA controlled substances for **Lim** whenever he was away on vacation or otherwise unavailable. Raquel works in Dr. Lim's next-door office and does not have prescription authority as a licensed health professional.

231. Raquel also informed **Relator** in response to **Relator's** inquiries made after two unsuccessful attempts for response by two of his colleagues and fellow staff Pharmacists about the lack of any tapering of **Beneficiary N.C.'s** oxycodone treatment, that **Beneficiary N.C.** had not been seen by **Dr. Lim** at all prior to receiving his prescription. Raquel further explained that she had written on a prescription form that had been pre-signed by **Lim**, using previously recorded prescription information, thus explaining the different handwriting on various prescriptions purporting to have been written by **Dr. Lim** himself.

232. After **Relator** informed Pharmacist-in-Charge Ramona Edery that the prescription at issue did not contain **Lim's** own handwritten date and **Relator** refused to fill the prescription, Edery filled **Beneficiary N.C.'s** prescription herself.

233. Additionally, **Relator** informed his Pharmacist-in-Charge Ramona Edery that he had clear evidence that **Dr. Davies** was likewise either post-dating prescriptions or leaving pre-signed pads that were used while he was on vacation or otherwise unavailable.

234. For example, **Relator** observed that an oxycodone prescription for **Dr. Davies'** patient **Beneficiary N.C.**, dated May 13, 2016 was delivered to **ModernHEALTH** on May 11, 2016.

2. Defendant ModernHEALTH's Falsification of Prescriptions to Circumvent ADAP's "Five Refill Rule."

235. In California, ADAP beneficiaries must have their ADAP-covered prescriptions reauthorized every six (6) months in order to maintain coverage. Thus, for a monthly prescription,

only claims submitted for payment for five (5) refills will be paid. California Department of Public Health, Office of Aids, AIDS Drug Assistance Program (CDPH/OA/ADAP/), Program Dispensing Policies, December 28, 2016, available at

https://cdph.magellanrx.com/provider/external/commercial/cdph/doc/en-us/CDPH_Formulary.pdf

“The claims adjudication system will accept five as the maximum number of refills.”

236. The public health rationale for this rule is clear: given the vulnerability of ADAP patients, the documented connection between HIV and substance-abuse, and, most critically the importance of ensuring that patients are adhering to their HIV treatment regimens to stop the spread of HIV, the government’s interest is to ensure that prescribers are exercising reason and medical judgment with regard to the appropriateness of ADAP beneficiaries’ prescriptions with sufficient frequency.

237. This public health rationale, however, stands in the way of Defendant Kroger f/k/a **ModernHEALTH**’s goal of maximizing gross receipts from government-funded drug sales, as it results in patients who are diverting, abusing or no longer in need certain prescriptions having their prescription reduced or denied.

238. In order to circumvent the five-refill rule and maximize the number of prescriptions filled and billed, **ModernHEALTH** AdRx Pharmacist-in-Charge Ramona Edery has, since not later than September 2015 and continuing, directed **ModernHEALTH** Pharmacy Technicians to falsify prescriptions by “splitting” single year-long prescriptions into two six-month prescriptions, taking advantage of the fact that doctors will routinely write year-long prescriptions for ADAP beneficiaries, either because they may not know the patient is an ADAP beneficiary or they simply rely on the screening mechanism created by the five-refill rule’s reauthorization requirement. The Pharmacy Techs are directed by Edery to complete this process without a signature or other

authorization from either the prescriber or a pharmacist in order to ensure the creation of a new prescription and future billable refills.

239. Rather than voiding half of the prescription, **ModernHEALTH** directs its Pharmacy Technicians to generate one legitimate prescription and one additional fraudulent prescription record entitled “Electronic Information for New Prescription from the Prescriber,” each indicating one-month supplies with five (5) refills. The forms are then stamped with a new expiration date and the label “Reassigned # of Fills.”

240. Two recent, representative examples of these fraudulently “reassigned” prescriptions illustrate the scheme as described below.

241. On June 14, 2016, Noreen Jack-Mooney, MD prescribed **Beneficiary W.S.** 90 Edurant tablets, an HIV medication, with eleven (11) refills. Rather than risk losing out on six (6) lucrative months of dispensing this \$1,138.95 per month medication, **ModernHEALTH** created fraudulent records to substantiate ADAP claims for payment for two separate five-refill prescriptions.

242. On July 13, 2016, Andres Marin, MD prescribed **Beneficiary G.G.** 30 Truvada tablets, an HIV medication, with twelve (12) refills. Rather than risk losing out on six (6) lucrative months of dispensing this \$1,294.56 per month medication, **ModernHEALTH** created fraudulent records to substantiate ADAP claims for payment for two five-refill prescriptions.

243. Although Defendant **ModernHEALTH**’s ADAP Pharmacy Benefit Manager will occasionally catch and reject these claims for “reassigned” claims as violating the five-refill rule, the vast majority of claims are nonetheless ultimately processed and paid as a result of the above scheme, resulting in hundreds of thousands of dollars in false claims for federally funded ADAP medications.

3. Defendant ModernHEALTH's Treatment of National Drug Code Changes as Prescription Refills in order to Fraudulently Extend the Life of Prescriptions.

244. National Drug Codes ("NDCs") are a unique 10-digit universal product identified for drugs in the United States. NDCs are published by the United States Food and Drug Administration ("FDA"). A drug's NDC code is specific to its manufacturer or "labeler." Thus, generic drugs from different manufacturers will have different NDCs despite having an identical chemical composition.

245. **ModernHEALTH** purchases generic drugs from its wholesaler, McKesson Corporation, who purchases them from various drug manufacturers. For example, **ModernHEALTH** carries generic levothyroxine, a common synthetic thyroid hormone used to treat patients with underactive thyroid, purchased by McKesson from manufacturer Caraco Pharmaceutical Laboratories Co.

246. Occasionally, when asked to fill a prescription for a generic drug, Pharmacy Technicians at **ModernHEALTH** will discover that the generic is out of stock with respect to its particular NDC Code. Because generics are chemically interchangeable, nothing in the CSA, DEA regulations, or California Pharmacy law prohibits the **ModernHEALTH** Pharmacy Technicians from filling a generic prescription with a drug that differs only by its NDC code.

247. **ModernHEALTH** and pharmacies in the industry commonly refer to this process as an "NDC change" or "NDC reassign."

248. When done properly, an NDC change is noted directly on the prescription, along with the original date of the prescription, the last fill date, and the number of remaining refills.

249. However, **Relator** is aware that since at least early 2012 and until late 2015, the Pharmacy Technicians at **ModernHEALTH** were trained to treat NDC changes as refills. **Relator** has personally observed this fraudulent scheme.

250. When executing an NDC change, **ModernHEALTH** Pharmacy Technicians were required to complete a **ModernHEALTH** “refill request form,” also referred to as a “P-label” rather than simply noting the change on the prescription copy itself.

251. By following this procedure, **ModernHEALTH** not only submitted false claims to the government for invalid refills of prescription drugs, but also illegally extended the expiration date of patients’ prescriptions and thus falsified documents to support its false claims for payment.

252. Prescriptions for drugs are good for one year, after which patient beneficiaries’ remaining refills are no longer valid. But each time a patient gets a re-fill via the NDC change, the one-year timer is re-set.

253. Thus, by treating NDC changes as refills, **ModernHEALTH** fraudulently extends the life of the prescriptions and the government pays for refills that have not been authorized by a physician and/or are expired.

4. Defendant ModernHEALTH’s Falsification of Prior Authorization Forms.

254. Prior authorization is a safety and cost-saving method used by, among others, Medicare Part D plan sponsors to determine if they will cover a prescribed procedure, service, or medication. Relevant factors include the patient’s age, medical necessity, the availability of a generic alternative, possible drug interactions, and expense. Whether prior authorization is required is most often determined within seconds by an automated program administered by the

insurer/Part D sponsor that is programmed to deny coverage subject to a prior authorization based on parameters that correspond to the above factors.

255. A failed prior authorization can result in coverage being denied, or an insurance company requiring the patient to go through a separate process known as "step therapy" or "fail first" whereby the patient must first see unsuccessful results from a medication preferred by the insurance provider, typically considered either more cost effective or safer, or both, before the insurance company will provide coverage.

256. After a physician orders a drug for a patient beneficiary, the physician's staff will contact the patient's insurer through the above described automated software to determine if they require a prior authorization check to be run. If so, a manual process is initiated. The process to obtain prior authorization varies from insurer to insurer, but typically involves the completion and faxing of a prior authorization form from a physician.

257. In the pharmacy industry, third-party administrators known as Pharmacy Benefit Managers ("PBMs") act as intermediaries between retail pharmacies and insurers, facilitating the payment of prescription drug claims including the prior authorizations.

258. In California, providers and other "risk-bearing organizations" including pharmacies are required to use the uniform Form 61-211 for prior authorization. 28 CCR § 1300.67.241.

259. Form 61-211 requires the name and contact information of the patient and the prescribing provider, as well as a description of the medication being prescribed, dosage, frequency, and duration of the drug therapy, patient's diagnosis, and, most importantly, "all relevant clinical information to support a prior authorization review" including "symptoms, lab

results with dates and/or justification for initial or ongoing therapy or increased dose and if the patient has any contraindications for the health plan/insurer preferred drug.”

260. Form 61-211 requires the prescriber’s signature. Under CHSC § 1467.241, a “prescribing provider” for purposes of completing a prior authorization form includes “provider authorized to write a prescription....”

261. To further its scheme, **ModernHEALTH** directs its Pharmacy Technicians through Pharmacist-in-Charge Edery in accordance with training processes approved by upper level management, to complete the prior authorization form *themselves* with the aid of commercial reference website <https://www.clinicalpharmacology.com/>.

262. Based on his personal observations and his review of prior authorization forms completed by **ModernHEALTH’s** own Pharmacy Technicians, **Relator** is aware that although some Pharmacy Technicians occasionally call the prescribing physician to at least learn the patient’s diagnosis, most rely solely on what they glean from the reference website, as Vice President Goodman and Pharmacist-in-Charge Edery have instructed their Pharmacy Technicians to “not call the doctors but do [their] own PAs.”

263. Finally, before submitting the prior authorization Form to the Pharmacy Benefit Manager, the **ModernHEALTH** Pharmacy Technicians use White-Out correction tape to conceal the word “Prescriber’s,” leaving only the word “Signature,” and then they sign the form themselves, as directed by **ModernHEALTH’s** management.

264. For example, on July 13, 2016, **ModernHEALTH** received a prior authorization request from Aetna, a large Part D sponsor, after a Pharmacy Technician had submitted a claim for payment for filling a #30 tablet prescription of Descovy, a new antiretroviral drug used to treat AIDS patient beneficiaries.

265. Rather than sending the prior authorization form to the prescribing physician, the **ModernHEALTH** Pharmacy Technician typically and in accordance with management directive, filled in the “required clinical information” box, without any medical consultation other than what he/she found on the internet, and recited “less risk of future renal toxicity” and “bone density toxicity” as the justification for the claim.

266. Then, the **ModernHEALTH** Pharmacy Technician used White Out to falsify the signature line of the form to make it appear as though only a “signature” and not a “prescriber’s signature” is required. The fraud is especially clear in this example because the Pharmacy Technician failed to adequately cover the word “Prescriber’s”, making the use of White Out readily apparent.

267. In addition to fraudulently altering and verifying prior authorization forms, Pharmacist-in-Charge Ramona Edery routinely instructs the **ModernHEALTH** Pharmacy Technicians to falsely tell the PBM representative verbally that they “spoke with the doctor’s office” or were “calling from [the prescriber’s] office,” when in fact both statements were knowingly false and made solely to obtain payments for false claims made to the government.

268. **Relator** is aware that **ModernHEALTH** Pharmacy Technicians are trained by **ModernHEALTH** Pharmacy Technician Managers to falsify prior authorization forms in this way as part of a corporate policy to assure that the maximum volume of prescriptions sales billed to the government are paid.

G. ModernHEALTH’s Identification, Concealment, and Failure to Report or Return the Overpayments that Resulted from its Submission of False Prescription Drug Claims.

269. In addition to verbally reporting medically unnecessary CSA controlled substance prescriptions to Pharmacist-in-Charge Ramona Edery beginning as early as February and March 2016, **Relator** informed both Edery and Vice President of Sales Brenda Goodman repeatedly including via emails on May 5, 2015 and May 19, 2015, before reaching out and reporting the violations to **ModernHEALTH**'s Human Resources department via emails to Human Resources Director Lori Galan on May 25, 2016.

270. After an ineffective early July 2016 meeting with Chief Administrative Officer Joan Schuckenbrock and Chief Operating Officer Thomas Dervin in which the violations reported by **Relator** as well as other AdRx pharmacists were treated as mere "communication" issues, **Relator** on or about July 15, 2016 called the local Drug Enforcement Agency ("DEA") office to report **Dr. Lim** and **Dr. Davies** for prescribing unreasonable, medically unnecessary and dangerous CSA controlled substances.

271. While **ModernHEALTH** continued to knowingly fill the illegal prescriptions, **Relator** on August 19, 2016 met privately with **ModernHEALTH**'s Chief Operating Officer Thomas Dervin during an on-site visit by Dervin to AdRx and further expressed to him that AdRx was committing dangerous fraud and retaliating against **Relator** and others when they refused or expressed reluctance to fill "red flag" controlled substance prescriptions and fulfill their "corresponding responsibility" as staff Pharmacists. Dervin stated that he would set up a call with **Relator** to follow up on the issues, but **Relator** never heard from him again regarding the controlled substance issues.

272. However, within a week of the August 19, 2016 conversation, Vice President Brenda Goodman was relieved of her AdRx pharmacy operations duties, a new CSA Schedule II controlled substance standard operating procedure was adopted ostensibly to facilitate meeting the

“corresponding responsibility” to identify “red flags,” and AdRx began transferring **Drs. Lim** and **Davies’** patient beneficiaries, and ceased filling controlled substance prescriptions written by **Lim** and or **Davies**.

273. Thus, at the latest, **ModernHEALTH** management, including Chief Operating Officer Thomas Dervin who reports directly to **ModernHEALTH’s** Chief Executive Officer Dom Meffe, had not only identified the claims for illegal controlled substance prescriptions by August 19, 2016, but also consciously declined to take steps to report them or to reimburse the government.

274. **ModernHEALTH** did not report any of its noncompliance or the resulting claims to the Government at all and certainly not within 60 days of August 19, 2016 or any of the above described “identification” dates.

VIII. MODERNHEALTH’s DISCRIMINATION AGAINST RELATOR FOR HIS COVERED CONDUCT.

275. **Relator** began attempting to stop false claims by halting the dispensing and questioning the reasonableness and/or medical necessity of **Defendants Lim** and **Davies’** CSA Schedule II prescriptions no later than February 2015 after noticing the pattern of “red flags” indicated that many of their patient beneficiaries were either addicted to or likely diverting their oxycodone.

276. After several months of regularly requesting additional documentation from **Lim** and **Davies** and expressing verbally and in writing his concern over and reluctance to fill their prescriptions to his Pharmacist-in-Charge Ramona Edery and her supervisor, Senior Vice President Brenda Goodman, **Relator** was threatened with termination by **ModernHEALTH’s** management.

277. Specifically, on May 19, 2016 during a discussion of his concerns with Edery and Goodman, **Relator** was vituperated by Goodman, who demeaned his professionalism loudly in front of his colleagues and made several insulting and threatening statements, including:

- “You wish you were a doctor, don’t you?!”
- “Do you really think we will need 4 pharmacists here if we lose Dr. Lim!?”
- “I’m protected, worry about yourself!”
- “If [Relator’s allegations] aren’t in writing, I’ll just deny it.”

278. Prior to this explosive meeting with Goodman and Edery, **ModernHEALTH** Pharmacists including **Relator** received an email from Edery addressing the “controlled substance issue” as a “problem in day-to-day business” not with regard to patient safety or the validity of the prescriptions, but with the Pharmacists’ “level of customer care,” meaning as an unacceptable impediment to dispensing, billing, and obtaining payment.

279. In response to Edery’s disingenuous email which ironically equated **Relator’s** desire to more closely examine the appropriateness of narcotic prescriptions with a lack of customer care, **Relator** stated in a May 19, 2016 email “[w]hen 4 pharmacists tell their PIC they are not comfortable filling Dr. Davies Prescriptions, our arms should not be bent to do so.”

280. Since the verbal and written exchange on May 19, 2016, **Relator** has attempted to stop false claims by raising his concerns regarding false claims in emails with Joan Schukenbrock, Chief Administrative Officer; Lori Galvan, Director of Human Resources; and Thomas Dervin, Chief Operating Officer, all acting on behalf of **ModernHEALTH**.

281. Most recently, **Relator** attempted to stop false claims by raising concerns regarding violation of anti-kickback laws with regard to **Dr. Lim’s** referral of patients in exchange for free drugs for him and filling the fraudulent Atripla prescription monthly for over five (5) years without charge to him.

282. From the time he first began attempting to stop false claims by raising his concerns in early 2015 to the present, **Relator** has been subject to pretextual disciplinary actions and general bullying by Edery and Goodman. For example, on August 24, 2016, Edery singled out **Relator** for tardiness and vague performance issues related to his “attitude.”

283. Moreover, **ModernHEALTH** has continued to pressure **Relator** into dropping his concerns and ceasing his conduct by which he has been attempting to stop false claims. Recently management accused **Relator** of discrimination when he followed up with **Dr. Lim’s** physician to verify **Dr. Lim’s** diagnosis as there are potential negative interactions between the Atripla medication and other prescribed medications.

IX. COUNTS

COUNT ONE

False Claims Act Claim, 31 U.S.C. § 3729(a)(1)(A) Submission of False Claims for CSA Schedule II Narcotics Fraudulently Prescribed and Dispensed

284. **Relator** reasserts and incorporates by reference all paragraphs set forth above as if restated herein.

285. This is a claim by **Relator**, on behalf of the **United States**, for treble damages and penalties under the FCA, 31 U.S.C. §3729(a)(1)(A).

286. Defendants submitted or caused to be submitted requests for payment to Medicaid, ADAP, and Medicare Part D Plan for dangerous CSA Schedule II drugs that were dispensed pursuant to invalid prescriptions. As a result, Defendants knowingly caused false claims for payment to be submitted to and paid by CMS for CSA Schedule II drugs that were ineligible for payment.

287. By virtue of the misrepresentations and submissions of noneligible claims described above, Defendants knowingly presented or caused to be presented to an officer or employee of the United States false or fraudulent Medicare or Medicaid or ADAP claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended by 31 U.S.C. § 3729(a)(1)(A).

288. By their fraudulent concealment, misrepresentations, falsification, and submission of ineligible claims described above, Defendants knowingly presented, or caused to be presented false or fraudulent claims capable of influencing the government's decision to pay, for improper payment or approval.

289. The United States, unaware of the falsity of fraudulent nature of Defendants' claims, paid the claims.

290. The United States has been damaged by all of the above misrepresentations and schemes to violate the requisite agreements and regulations in an amount which is yet to be determined. With respect to the said misrepresentations and failures to comply, Defendants knowingly made or caused to be made false claims to officials of the **United States** for the purpose of obtaining compensation.

COUNT TWO

False Claims Act Claim, 31 U.S.C. § 3729(a)(1)(B) Falsification of Medical Prescription Records in Support of False Claims.

291. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.

292. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §3729(a)(1)(A).

293. Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment to CMS for Schedule II drugs that were ineligible for payment.

294. By virtue of the misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to an officer or employee of the United States false or fraudulent Medicare claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended by 31 U.S.C. § 3729(a)(1)(A).

295. By their fraudulent concealment, misrepresentations and submission of non-reimbursable claims described above, Defendants knowingly presented, or caused to be presented false or fraudulent claims capable of influencing the government's decision to pay, for improper payment or approval.

296. The United States, unaware of the falsity of fraudulent nature of Defendants' claims, paid the claims.

297. The United States has been damaged by all of the aforementioned misrepresentations and failures to comply with requisite agreements and regulations in an amount which is yet to be determined. With respect to the said misrepresentations and failures to comply, Defendants knowingly made or caused to be made false claims to officials of the United States for the purpose of obtaining compensation.

COUNT THREE

**Stark Law, 42 U.S.C. § 1395nn
Defendant Lim's Illegal Referrals to Defendant ModernHEALTH**

298. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

299. Defendants, through the practices described above, intentionally violated Stark, 42 U.S.C. § 1395nn by Defendant **Dr. Lim** making referrals of Medicare and Medicaid patients to Defendants Kroger Specialty Pharmacy Inc. f/k/a Modern HC Holdings, Inc. and Kroger Specialty Pharmacy CA 2, LLC f/k/a ModernHEALTH Specialty Ad-Rx, LLC (collectively “Kroger Specialty Pharmacy f/k/a ModernHEALTH”)

300. Under Stark, a “financial relationship” consists of a “compensation arrangement.” A “compensation arrangement” is any arrangement involving any remuneration between a physician and an entity, subject to certain exclusions. 42 U.S.C. § 1395nn(h)(1)(A). “Remuneration” includes any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, subject to certain exclusions. 42 U.S.C. § 1395nn(h)(1)(B); 42 C.F.R. § 411.351. No exclusions apply in this case.

301. Defendants through the practices described above intentionally violated Stark, 42 U.S.C. § 1395nn by submitting claims to Medicare and Medicaid and ADAP for those services resulting from prohibited referrals of designated health services from a physician.

COUNT FOUR

Anti-Kickback Statute, 42 U.S.C. § 1320a-7b Defendant Lim’s Illegal Referrals to Defendant ModernHEALTH.

302. Relator re-alleges and incorporates by reference the above allegations as if fully restated herein.

303. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the

purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). Compliance with the Anti-Kickback Statute is a precondition to participation and payment as a health care provider under a Government Health Care Program.

304. By virtue of the acts described above, Defendant **Lim** and Defendants Kroger Specialty Pharmacy Inc. f/k/a Modern HC Holdings, Inc. and Kroger Specialty Pharmacy CA 2, LLC f/k/a ModernHEALTH Specialty Ad-Rx, LLC (collectively “Kroger Specialty Pharmacy f/k/a ModernHEALTH”) engaged in an illegal kickback scheme in which Defendant Lim was induced to and rewarded for referring patients to **ModernHEALTH**.

305. Claims for reimbursement for services that result from kickbacks are false under the False Claims Act, 42 U.S.C. § 1320a-7b(g), rendering all claims for outpatient prescription drugs submitted by Kroger Specialty Pharmacy f/k/a ModernHEALTH for filling those prescriptions written by Lim false.

COUNT FIVE

California False Claims Act, Cal. Gov’t Code § 12650-56 Submission of False Claims for CSA Schedule II Narcotics Fraudulently Prescribed and Dispensed

306. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

307. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov’t Code § 12650-56

308. By virtue of misrepresentations and the causing of submissions of ineligible claims described above, Defendants knowingly presented or caused to be presented to the California Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly

accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

309. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

310. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

311. Further, by retaliating against Relator as described above, Defendants violated the anti-retaliation provision of the California False Claims Act, § 12653(a).

COUNT SIX

False Claims Act, 31 U.S.C. § 3730(h) Retaliatory Discipline, Harassment and Threats Against Relator.

312. As his claim against **Kroger Specialty Pharmacy Inc.** f/k/a Modern HC Holdings, Inc. and **Kroger Specialty Pharmacy CA 2, LLC** f/k/a ModernHEALTH Specialty Ad-Rx, LLC (collectively Kroger Specialty Pharmacy f/k/a ModernHEALTH) Relator re-alleges and incorporates by reference all paragraphs set forth above as if restated herein.

313. 31 U.S.C. §3730(h), provides, “(1) Any employee... shall be entitled to all relief necessary to make that employee... whole, if that employee is... discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee... in furtherance of, other efforts to stop one or more violations of this subchapter.”

314. Relator was discriminated against in the terms and conditions of employment when his lawful attempts to stop Kroger Specialty Pharmacy f/k/a ModernHEALTH continued submissions of false claims were met by Kroger Specialty Pharmacy f/k/a ModernHEALTH with

retaliatory pushback from Kroger Specialty Pharmacy f/k/a ModernHEALTH, specifically: initiation of multiple pre-textual disciplinary proceedings, reprimands, and write-ups.

COUNT SEVEN

False Claims Act, 31 U.S.C. § 3729(a)(1)(G) ModernHEALTH's Failure to Report and Return Overpayment Within 60 Days of Identification

315. Relator re-alleges and incorporates by reference all previous paragraphs.

316. The False Claims Act, 31 U.S.C. § 3729(a)(1)(G), imposes liability on any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

317. Defendant ModernHEALTH knew no later than August 19, 2016 when Relator spoke to Chief Operating Officer Thomas Dervin about the medically unnecessary controlled substance prescriptions being fraudulently filled and billed at AdRx after months of back and forth with mid-level managers Ramona Edery and Brenda Goodman regarding the same issues, that it needed to review its records for the noncompliance in drug payment claims submitted to the Government through their PBM and Part D Sponsors and that it needed to reimburse the United States and California for overpayments.

318. Instead, **ModernHEALTH** decided to turn away the patients of **Dr. Lim** and **Dr. Davies**, thereby making their medically unnecessary controlled substance prescriptions somebody else's problem while ModernHEALTH covered up their role in the scheme with the issuance of new boilerplate standard operating procedures.

319. Thus, Defendant **ModernHEALTH** identified overpayments no later than August 19, 2016 and by their subsequent actions expressly indicated that they were aware of their noncompliance and thus they were required to exercise reasonable diligence in looking back through their billing records and reporting their false claims within 60 days, or at all. See 42 C.F.R. §§ 401.301 - 401.305.

320. Through the acts described above, Defendant **ModernHEALTH** knowingly concealed money that was owed to the Government when **ModernHEALTH** failed to return to the Government payment received for drugs Defendant knew were not dispensed pursuant to valid prescriptions or otherwise did not qualify for reimbursement under the ADAP, Medicaid, and Medicare programs.

321. The United States and State of California have been damaged by all of the above fraud and illegal conduct in an as of yet undetermined amount.

322. Defendant **ModernHEALTH** knowingly made false claims to officials of the United States and State of California for the purpose of obtaining compensation and Defendant received such compensation from the Government as a result of Defendant's false claims.

X. PRAYER FOR RELIEF

WHEREFORE, Relator, the United States, and the State of California is entitled to damages from Defendants in accordance with the provisions of 31 U.S.C. §§ 3729-3733, and Plaintiff/Relator requests that judgment be entered against Defendants, including that:

- a. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*;

- b. Defendants pay an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty against Defendants of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729 committed on or before November 1, 2015; and not less than \$10,781 and not more than \$21,563 for each violation of 31 U.S.C. § 3729 committed after November 2, 2015 pursuant to §3729 (a)(1) and 28 C.F.R. § 85.5 (effective August 1, 2016), or as may be further adjusted;
- c. Plaintiff/Relator be awarded the maximum amount allowed as a Relator share pursuant to 31 U.S.C. § 3730(d);
- d. Plaintiff/Relator be awarded such relief as is appropriate under the provisions of 31 U.S.C. §3730(h) of the False Claims Act to make him whole for the damages and financial losses suffered as a result of the discrimination against him in the terms and conditions of his employment including litigation costs and reasonable attorneys' fees;
- e. An injunction be issued to permanently restrain and enjoin Defendants, their agents, employees, and administrators from harassing, retaliating or otherwise discriminating against Plaintiff/Relator or any other person who objects to, protests or discloses fraud or otherwise engages in protected activities within the meaning of the Section 3730 of the FCA;
- f. Plaintiff/Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d);
- g. Plaintiff/Relator be awarded all damages and penalties available under the California False Claims Act, Gov't Code §§ 12650-56; and

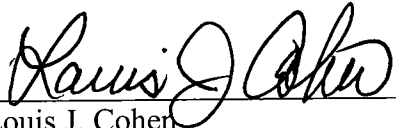
h. The United States, California and Plaintiff/Relator be granted all such other relief as the Court deems just and proper.

Demand for Jury Trial

Please take notice that the Relator demands this action to be tried to a 12-person jury.

Respectfully submitted and dated this 16th day of March 2017.

Louis J. Cohen, a Prof. Corp.
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ERL Medical Corporation
Emmanuel R. Lim, MD
Douglas Davies, M.D.
Louis Flores, MD, and
The Doctor Health Center, Inc.